



# QUALITY MANAGEMENT GUIDE

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## Contents

Introduction .....	5
Chapter 1: Transplant Centre Organisation & Development.....	9
Chapter 2: Document Development, Implementation, Control, Review & Archive .....	39
Chapter 3: Errors, Accidents, Adverse Events, Biological Product Deviations & Complaints .....	65
Chapter 4: Audit, Validation, Product Tracking, Outcome Analysis & Performance Measurement .....	81
Chapter 5: Writing & Reviewing the Quality Manual.....	123
Chapter 6: Maintaining the Quality Management Programme.....	131
Acknowledgements .....	137



# *Introduction*

## **How to Use the Quality Management Guide**

Quality Management is used in organisations and industries worldwide and there is no “best way” to develop a quality programme – it depends upon the type of organisation you work for and what the objectives of the organisation are.

## **What is this guide for?**

This Quality Guide is designed to assist in the development and maintenance of a Quality programme for the area of Peripheral Blood and Bone Marrow Stem Cell Transplantation.

## **Where did the idea come from?**

The idea for a Guide was presented to the EBMT in 2006. A working group was established and chapter outlines were developed. An Editorial Review Committee read the outlines and, following several suggestions and changes, the final Guide was written, reviewed and agreed for publication.

In 2012, the JACIE Quality Management Committee decided to update the manual in order to bring it into line with the 5<sup>th</sup> edition of the FACT-JACIE standards and also to include guidance aimed at the many centres that now have active quality management systems in place for several years.

## **How might this guide help centres?**

This Guide provides scenarios and example templates from JACIE-accredited centres to assist the reader with the implementation and maintenance of a Quality Management Programme and to support the quality Standards contained within the FACT-JACIE International Standards, 5th Edition (March 2012). The templates provide examples of how some of the systems **could** be set up within your centre, but they

do not have to be used if you have an alternative approach which works better for you.


Important – Following the suggestions and examples in this Guide is NOT a guarantee that accreditation will be achieved.

### **What audience is the guide aimed at?**


The Guide is designed for use by teams who work in the Transplant Setting. It should be simple and easy to follow.

### **How do you use the guide?**

The Guide is split into sections – you may not need to look at every section because you may already have systems in place for some of the quality Standards required.

Examples or scenarios from other Centres showing how they have approached an aspect of quality management are shown in *italics* with the  symbol. These are designed to describe what has been done to support implementation of quality programmes in other centres.

The end of each Chapter contains **Example Templates** and **Worksheets** which you can use or adapt as a basis to set up your own system.

Common deficiencies noted in past inspections are shown next to a symbol like this 

The type of deficiencies noted and their corrective actions will be provided as examples.

### **What if I need further help?**

Contact details of people who can provide further assistance are provided at the end of the Guide.

We hope you find this issue of the Quality Management Guide useful and that it assists you in developing your quality programme. Please

remember that Quality Management needs to be supported across the programme by **all** of the team in order to ensure its success and maintenance.

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# ***Chapter 1: Transplant Centre Organisation & Development***

*JACIE Standards: B/C/D4*

## **Introduction**

Development of a comprehensive Quality Management Plan (QMP) or Quality Manual (QM) is often the most challenging and time-consuming exercise that the Transplant Programme encounters when preparing for FACT-JACIE accreditation.

In simple terms the Quality Management Plan (Quality Management Manual) is an A-Z of your Transplant Programme.

The Quality Management Plan (Quality Management Manual) consists of:

- A description of how the programme was developed.
- Organisation structure, listing the whole team and their roles/responsibilities.
- Details of associated consulting specialists.
- Defines the number and types of transplants carried out.
- How the programme Quality Management Systems are implemented such as holding quality management meetings, documenting personnel education, experience and training requirements, outlining the process for adverse event reporting, investigation and dissemination, etc.
- Associated Policies and Procedures which drive the operation of the Quality Management Plan.
- Defining a system for recording and determining medical staff's initial competency, training and continued competency at least annually.


The Quality Management Plan (Quality Management Manual) should be one of the first documents developed when preparing for a JACIE

inspection. This is because it takes a considerable amount of time to prepare; typical questions to ask in order to draft this document are:

What type of Transplant Centre do you work in? For instance, are you:

- A Centre which provides transplantation, collection and processing?
- A Centre providing one type of Transplant and using a Third Party for your Collection and Processing needs?
- A Centre which provides Autologous and Allogeneic transplant using a Third Party for your Collection and Processing Needs?
- A Centre which provides Transplantation and Bone Marrow Collection on the same site but uses third party for PBSC Collection and Processing?
- A Centre which provides collection and processing only?
- Does your centre look after Adult and/or Paediatric Patients?

The Quality Programme should be designed to fit the organisation of your Centre.

 *If you use a third party collection and processing service then perhaps they have a quality programme already established. This is perfectly acceptable - what you need to think about is how the Clinical programme can link and integrate with the third party's quality programme. Examples of how this is achieved in other Centres are shown below.*

<b>Find out</b> Do you work with a third party who might already have a Quality Programme?
--

**Arrange** To meet the Quality Manager of the third party centre (if applicable) so that you can talk through what you are trying to achieve.

If you do not use a third party then you must implement a Quality Programme which covers every part of the Transplant process. Later in

the guide, further examples from different types of centre will be shown.

The Quality Management Plan or Manual must include a summary of how the Centre records personnel education, experience, and training requirements for all medical staff (consultants, junior doctors and nurses). This includes competency for each function performed which needs to be repeated at least annually. A description of the process for annual performance review and provisions for continuing education also needs to be included (Example 4: Template used to log Annual Record of Educational Activity in SCT)

### **The Role & Responsibilities of the Quality Manager or Person Designated as Responsible for the Setting-up and Maintenance of the Quality Programme**

Depending on how your Centre is organised may be only a single Quality Manager or a separate Quality Manager for each section i.e. Clinical, Collection and Processing. Overall responsibility for the Clinical quality programme lies with the Clinical Programme Director or a designee (normally the Quality Manager).

The role of the Quality Manager includes but is not limited to;

- Understand the entire Transplant Process from start to finish.
- Facilitate the development of documentation and improvements to standardise and enhance the overall service.
- Support the Director and encourage/educate the entire team in establishing and sustaining a quality management culture.
- Coordinate the quality programme.
- Report & Communicate on the Quality Management activities at a minimum quarterly.
- Communicate regularly with transplant programme staff (e.g. Collection, Nursing, Administrative, Laboratory, Consultants, Junior Doctors, Data Managers).
- Be visible within the Centre

- Motivate people.

The Quality Manager is responsible for the development, implementation and maintenance of the Quality Programme and its components as described in this Guide and the JACIE Standards. The Clinical Programme Director and respective Collection and Processing Directors have overall responsibility for the Quality Programme as part of the overall JACIE requirements.


The Quality Manager must understand how the transplant process works (allogeneic, autologous etc) and the steps which patients and/or donors follow for example:




*To understand the collection part of the Transplant process, you could follow a patient and/or donor through the process of Bone Marrow or Peripheral Blood Stem Cell Collection to see what steps the patient/donor and the Cells go through.*

- *To understand the same part of the Transplant process from the patient's perspective, you could ask the patients what they thought: Did they get all the information they needed? Was the procedure as they expected?*
- *To understand the same part of the Transplant process from the Staff perspective, you could observe them while they see a few patients all undergoing the same procedure, then ask questions about how and why things are done in a particular way and if there is another way to do it.*

In order to be able to understand the processes generally, you need to be visible which means going and talking to people about what they do. If you are the Quality Manager of only one part of the programme (e.g. Clinical) then you will need to provide evidence of interaction between the other sections.

 A combined Adult and Paediatric Centre may use a third party for PBSC collection and processing BUT performs bone marrow harvesting in-house. The Clinical Quality Manager is also responsible for ensuring the Quality Programme covers the Bone Marrow Collection part of the process. This means understanding how Bone Marrow Harvests are arranged and undertaken; making sure that all procedures are in place for safe Bone Marrow Harvesting. The Bone Marrow Harvesting Policies and Procedures were developed with the integration of Theatre Staff, Anaesthetists, Physicians, Nurses, Coordinators and the Processing Centre. The Processing Centre undertakes Peripheral Blood Stem Cell Collection as well and has its own Quality Manager. Both Quality Managers hold regular meetings and have developed either an integrated manual to show where lines of responsibility start and end or have two separate quality manuals. Integration is shown via the same format for documentation and document control, regular meetings between all parties, combined audits and sharing of good practice. The Serious Adverse Event Reporting systems need to be robust in order for information about each section to be shared.

- A combined Clinical and Collection Centre uses a third party for Processing. The Processing facility has its own Quality Manager therefore the example above applies.
- A Centre with one Quality Manager for everything has the same requirements for standardised document format and control, meetings with staff from each of the areas and audits of all three parts of the process as above.

 Evidence of integration

- Minutes of Quality meetings between the Clinical, Collection and Processing facilities.
- Policies and Procedures should be designed in a standardised layout. Example Templates are shown in Chapter 2.

- *One system for reporting, investigating and correcting Adverse Events. This could be the hospital system but it must be clear how transplant-related issues are notified and reviewed.*
- *One Audit Schedule.*
- *Policies, Procedures and Worksheets should state clearly what each area's responsibilities are e.g. The procedure for Collection of Cells should provide a stepwise instruction of what happens to the patient and who provides the input at each stage. These documents should therefore be written with all sections involved.*
- *Your Institution might have a department or person responsible for development of third party agreements (e.g. your contract or Service Level Agreement (SLA) with a donor registry). Find out who/where this person/department is and ask them how such agreements are developed.*
- *Your Centre should have identified a Collection and Processing Facility and Medical Director or designated person. If they are not directly employed by the same institution, these individuals might need honorary contracts. An honorary contract gives individuals the right to work in more than their own institution and is good evidence of integration across different organisations. Find out if this is the case and whether or not they are already in place.*

## **Describing the Transplant Programme Organisational Structure**

One of the aims of the Quality Management Programme should be to improve communication and understanding of roles and responsibilities across all of the different staff groups within the Centre. Poor Communication between groups of staff is cited as one of the biggest single causes of Quality Programme failure<sup>1</sup>.

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<sup>1</sup> Bell, D., McBride, P. and Wilson, G. Managing Quality. Oxford, Butterworth, 1994

To improve communication between staff and departments to ensure that everybody is clear about roles, responsibilities and levels of authority for decision-making, you could start by understanding what the centre structure is and how different departments/staff interact with each other. The JACIE standards require that the Quality Manual includes an organigramme or organisational chart. This means that the Centre should develop an organisational chart which describes the structure of all parts of the Transplant Programme and who is responsible for what aspects (Collection/Clinical/Processing). The chart should illustrate who reports to whom and who has **overall** responsibility for the different aspects of the transplant programme (*See Example 2 Templates at end of this Chapter*). The structure will enable both new/existing staff and external organisations e.g. donor registries to easily identify the make-up of the programme and lines of command. Patients could also be provided with information about the team who are looking after them.



*The type and size of the chart will depend upon which type of centre you are:*

- *If you are a centre with a third party providing Collection/Processing services, then your chart might be a little more complicated as you need to show how the different bits fit together. You will need to show where the collection/processing takes place and the individuals involved with this.*
- *You will need to discuss and agree the organisational structure of your programme and assign clear roles – this will help you from the start of your Quality Management Manual. You need to show how each of the three sections – Clinical, Collection and Processing are managed and where they are based. Staff must accept their roles and know what is expected of them.*
- *You will need to show the lines of communication and responsibility across and throughout the entire programme.*
- *All Centre staff should have clearly defined roles and responsibilities and these should be shown on the organisational chart. This information could then be further*

*explained in your Quality Manual especially the responsibilities and if possible Job Descriptions or at least where they are located.*

- *Search the Internet for resources for this purpose or alternatively you can develop one in-house e.g. using PowerPoint.*

## **Personnel Qualifications, Training & Competency**

JACIE STANDARDS: B/C/D4.3

It is important for any organisation to ensure that staff have the knowledge, experience and are adequately trained to perform the tasks required of them. This training can be as simple or as complex as the task itself, and can be run either within the organisation or by an external body such as a university. For every role within the Transplant programme there are basic educational and experience requirements which should be stated in the Job Description (*see Example 1*). There is also a requirement for all staff to receive training specific to their role once they have taken on a post e.g. using an apheresis machine and administering cytotoxic chemotherapy. Some medical staff such as junior doctors might only spend a short time within the Centre before moving on elsewhere, therefore this type of training is especially important. Staff should receive both theoretical and practical training for all necessary tasks and then have their competency to perform these tasks documented by a designated member of staff. If and when practice changes as a result of Policy or Standard Operating Procedure change then any training requirements will need to be considered and implemented. Refer to Example 7 *Check-List for All SCT Nursing Staff Record Training & Competency/Supervised Procedure.*

### **Minimal Trainer Qualifications**

The type of qualifications trainers should have depends on the type of training they are providing. This can range from a formal teaching qualification for nurse educators running educational programmes to the person being designated as 'competent' to train staff in a particular



procedure. This will be governed by local and national requirements but in the first instance should be based on the qualifications of existing trainers (unless these do not meet national standards). If a Centre has no existing trainers then either new staff should be recruited or existing staff identified who can take on this role.




- *Do you have someone responsible for the Training Programme for Nurses, Medical and other Transplant staff?*
- *Do you have a Policy for Training which states how and when staff should receive their training?*
- *Does a member of staff or someone else hold documents or a database that shows when training has been completed?*
- *Does your institution have a series of mandatory training courses which staff must attend?*
- *Do members of staff have a personal record of the training they have undertaken?*
- *All staff should have an Induction or Orientation Course covering general points of awareness related to the hospital/clinical Haematology (SCT) Centre and a record of attendance must be kept for every induction session held.*
- *Your QMS should build in a process to measure competency, this should be summarised within the Quality Manual, such as supervised 'hands-on' training for practical procedures or comprehension/multiple choice questions related to procedures to show that staff have understood the procedures and are capable of following them.*

## **Curriculum Vitae & Registration of all Transplant Physicians and Key Personnel**

A *curriculum vitae* is used to describe the career history of personnel and it is a requirement of JACIE that CVs are collected from Physicians, Facility Directors and other key personnel within the programme. Some peoples CVs run to many pages and on the JACIE website there is a concise CV template which can be downloaded so

that there is a standard approach to length and content. It is important that the history around Transplant related experience and knowledge is clearly shown on the CV.

Along with CVs it is a requirement to document registration of medical staff with the relevant national or regional organisation e.g. General Medical Council in the UK.

 *Some centres have collected CVs and have added additional statements from the team specifically giving examples of their transplant-related positions held, training undertaken, conferences attended and literature published.*

## **Training/Competency**

**Initial Qualifications** – *This means that Basic Qualifications required for each post should be detailed in the Job Description e.g. the position requires a Nurse to be trained and registered in order to work in a Transplant setting. The basic qualifications required for each role within the three sections of the programme need to be agreed with the management team i.e. Physician/Head of Department/Human Resources based upon local and national requirements. Each area of the programme will probably already have agreed these for existing staff, therefore, it will only be necessary to put a system in place to show how new positions and the qualifications required for them are agreed. You could talk to your Human Resources Department, the Lead Nurse or a Physician about how this is currently done for existing positions.*

**Orientation** – *This means a programme for any staff group which includes providing general information about the Centre. Examples include an Induction/Orientation within the first few weeks of starting in the Centre in order to meet the key people so that they can be shown the systems and processes in place across the programme and how each of these interacts with one another.*


**Initial Training** – *This should cover the key tasks which staff need to know immediately on starting in a new role or if practice is changed at any time. This could take the form of practical on-the-job training or could take the form of a workbook to be completed within an agreed timescale. It is the Centre’s responsibility to define the initial training requirements and these should be documented. The type of training required can be identified using a Training Needs Analysis – this defines the competencies and behaviours required for each role. Requirements can be developed for groups of staff and then every individual within each group is required to be documented that they have completed it. It is the relevant Head of Staff (Nursing, Medical, Laboratory etc) who is responsible for ensuring that this initial training is undertaken in a timely manner.*

**Competency for Each Function Performed** – Competency means ability to carry out requirements of any post safely and within required procedures. Many institutions may already have competency frameworks for areas such as cytotoxic chemotherapy or general haematology. Transplant competency requirements should be included in a training log and/or workbook as evidence that theoretical knowledge has been obtained. The log/workbook should also include sections for practical observation e.g. the trainer observes the staff member performing the task (e.g. administering cytotoxic chemotherapy) and then if satisfied, confirms competency by signing the record.


### **Continued Competency at Least Annually**

Competency can be assessed in several different ways:


It can be in the format of an **Annual Performance Review** where the member of staff’s strengths and areas for improvement are discussed. This also identifies any training completed in the preceding year and identifies training needs for the coming year.

 *Are there records of annual performance reviews performed? If so, find out who holds and updates them and write down the details. Your institution might have a policy for Training and Development which includes Performance Review and how to perform it and how often – locate a copy of this policy for your records or refer to it from your Quality Manual.*

Some **training** should be repeated regularly by staff e.g. safety procedures such as fire, health & safety, manual handling, etc


 *JACIE provides information on those competencies which should be performed annually for staff. There will also be institutional and national mandatory requirements for specific competency assessment e.g. cytotoxic chemotherapy competency. Decisions about which competencies should be included should be based on legal requirements in your country and local needs e.g. manual handling, infection control, etc.*


Evidence of **continued medical/professional development** (CMD/CPD) can also be used.

 *Certificates of attendance at conferences and meetings (EBMT/CIBMTR etc), external training courses*

### **Provision for Continuing Education, Training & Re-Training**

A detailed education programme should be produced for each staff group. This should include all educational updates required to meet the institutional and Centre requirements as well as requirements of national governing bodies. Retraining requirements for all statutory and institutional training needs should be defined e.g. to remain on Intrathecal Chemotherapy Administration Register, staff must be assessed at a minimum annually. See Example 8 *Example of an education & training for junior medical staff.*


 *In some centres there are Folders held by staff in which they put documents as evidence of their continued professional development and continued competency assessment. Your institution might have these or something similar.*

 *Regular Educational sessions for staff are run by Centres. These include Journal Clubs which are a regular meeting at which staff discuss published articles about developments in their field.*

- *Nurse Educational Study days are run in centres. The study days start with an overview of the quality programme and developments such as new systems and then invited speakers and lecturers provide training on the transplant specific competencies including: Safe Infusion of Cells, High Dose Therapies, Apheresis, Bone Marrow Harvesting, Blood and Blood Products and so on.*
- *Centres hold regular Morbidity and Mortality Meetings. These are attended by everyone who has looked after the patient being discussed and personnel with an interest in the outcome of the patient following the treatment given. These meetings can take the form of a presentation about the patient including initial diagnosis, treatment prior to transplant, the transplant phases, the patients outcome, what went well or less well and any lessons learned. Meetings can be held monthly or less frequently.*

### **Uniform Plan for Staff Training**

There should be documented evidence of a plan for ensuring all staff remain trained to a suitable standard and are only performing procedures they are deemed competent to perform.

 *This could be in the form of an individual record of when training was last completed and when training should be repeated or the training requirements could be included within the procedure itself.*

*Also a rolling programme of training to ensure all staff receive training regularly e.g. programme for training of junior medical staff that covers rotational changes, regular updates of staff who perform complex procedures such as apheresis or bone marrow harvest and cell reinfusion training. See Example 8 Example of an education & training for junior medical staff.*

## **Communication, Groups & Meeting Development**

A Quality Programme will only be successful if there is regular communication between all of the staff involved. There are a variety of group and team meetings which have been established in other Centres to demonstrate integration and ensure the systems in place work together.

**Examples of Template Agendas and signing in sheets which act as evidence of meeting progress and integration are shown at end of this chapter.** Refer also to Example 9 *Suggestions of Stem Cell Transplant Team Meets & their Frequency.*



- **Quality Management Group** – *This group should generally be chaired by the Quality Manager. Attendees may include; the Programme Director, Medical Staff, Senior Nursing Staff, Pharmacists, Data Managers, Collection facility staff, Processing facility staff, Laboratory staff and Clinical Trials staff. In some Centres, the agenda for this meeting includes SOP development/review, audit timetable development, incident reporting, training/educational programme development and service improvement.*
- **Clinical Policy Group** – *There are a lot of Clinical Policies required for the Quality Programme and in some Centres a structured approach to development of these is to form a specific working group including Transplant Physicians, Collection/Processing, Nursing, Pharmacy and support staff.*

*This does not have to be separate to the Quality Management Group and could form part of the same meeting.*

- ***Morbidity and Mortality Meetings*** – *These meetings and presentations of specific cases allow treatment pathways and outcomes to be discussed. The group is usually multidisciplinary with attendees including Transplant Physicians, Nursing staff, Collection/Processing and other Support Service staff.*
- ***Stem Cell Facility User Group Meetings*** – *In centres where a separate collection and processing facility is used (third party), meetings are hosted by the third party facility in order to discuss issues around the service provided. The agenda can include document development where documents are linked i.e. Product Delivery to the Centre, Incidents with product delivery, Biological Product Deviations.*
- ***Management Review Meetings*** – *These meetings can be held to look at the entire quality programme and attendance includes all Directors, Quality Manager, Nursing and Medical staff.*

You might have meetings already established but with different titles. You might meet with different frequently. The important point is that you regularly communicate with all of the transplant service providers. Some Centre Quality Managers attend ward meetings, staff meetings, handovers and so on in order to bring quality issues to the ward; rather than having specific separate meetings.



## **Some Examples of Common Deficiencies**

### *Single Programme Not Fully Integrated*

*One noted deficiency in a Centre providing both adult and paediatric transplants was that the programme was not fully functioning as a single programme as defined in the standards in the areas of common training and quality management programmes and the use of the same clinical protocols in all areas. The Quality Programmes were separate and despite agreement that there would be joint quality management meetings, these had not taken place. It was recommended that there should be more integration with common procedures, training and more joint meetings i.e. for adverse event review, outcome review, scientific and educational meetings.*

### *Quality Management*

*While the programme satisfies the standard in that they have a Quality Programme under the supervision of a single designated person, in practice there are two programmes each with a medical and nurse lead. It was not clear who was the person responsible for quality management.*

### *Training*

*The nurses at the centre should participate in common training programmes.*

*The competency of technical staff is documented prior to beginning assigned procedures but not at regular intervals thereafter.*

*Generally, it is difficult to verify from the CVs provided the individual's training in stem cell transplantation – this needs further clarification.*

### *Communication*



*Written orders from the clinical facility to the collection facility prior to PBSC collection were not available. Evidence that order forms for collection from a physician regarding timing and procedural details and goals of collection should be submitted.*

*There is no written order for the collection sent from the transplant team to the collection facility prior to collection.*

### Example Templates Provided For This Section

Number:	Title:
1.	Example QM job description
2.	Template Organisational Chart
3.	List of the personnel who work within the Transplant Programme at the Centre who could appear in the organigramme
4.	Sample template of written description of the organisation chart
5.	Example template agenda for a monthly quality group meeting
6.	Template used to log Annual Record of educational Activities SCT
7.	Check-List for All SCT Nursing Staff Record Training & Competency/Supervised Procedure
8.	Example of an education & training for junior medical staff
9.	Suggestions of Stem Cell Transplant Team Meets & their Frequency

## **1. Example QM Job Description**

**Title:** Quality Manager for Bone Marrow  
Transplant Services

**Directorate:** *is there a specific area i.e. Haematology*

**Board/corporate function:** *i.e. the Hospital Board*

**Band/Grade:** *What is the grade of the job i.e. salary scale*

**Responsible to:** *Programme Director*

**Accountable to:** *Head of Department*

**Hours:**

**Location:** *Is the job on one site or several sites?*

### **JOB PURPOSE**

***What is the job being designed for?***

*you would write in here about what the Quality Manager is expected to achieve – the outcome i.e. initial JACIE accreditation and maintenance year on year in preparation for re-inspection*

### **DIMENSIONS**

**Key working relationships:**

***Who will the Quality Manager be working with***

***What are the duties of the Quality Manager***

*The duties described earlier in the chapter and the remainder of this Guide*

### **KEY RESULT AREAS**

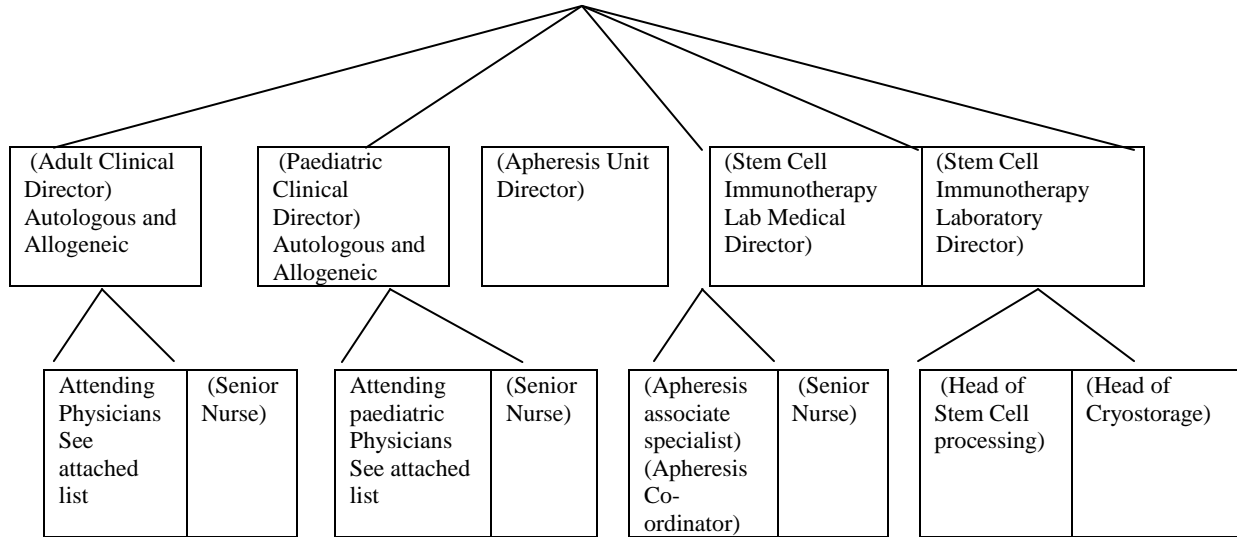
***What are the objectives to be achieved by the Quality Manager?***

## 2. TEMPLATE ORGANISATIONAL CHART

### Bone Marrow Transplant Programme

Hierarchy

(Programme Director)



**This layout shows all parts of the Programme. Add the names of the individuals for easy identification.**

### **3. List of the personnel who work within the Transplant Programme at the Centre who could appear in the organigramme**

If you list the personnel then you should also describe what their responsibilities are.

- Adult Attending Physicians
- Paediatric Attending Physicians
- Bone Marrow Transplant Unit (BMTU) and Oncology Day Beds Unit (ODB) Senior Nurses and Education Sisters
- Nursing Quality Management Lead
- BMT Ward Manager
- ODB Ward Manager
- Clinical Risk lead
- BMT Education Sister
- Paediatric Haematology/Oncology Education Sister
- BMTU Coordinators
- Nurse Coordinator
- BMT Medical Coordinator
- Donor Coordinator
- Programme Pharmacists
- BMT Pharmacist
- Pharmacist
- Clinical Programme Quality Manager
- Clinical Programme Data Manager
- Clinical Programme Infection Control Lead
- Apheresis Unit and Stem Cell Immunotherapy Department Hierarchy
- National Blood Service Quality Management
- Quality Assurance Manager
  - Assistant Quality Assurance Manager
  - Assistant Quality Assurance Manager

**4. Sample template of written description of the organisation chart 2 (previous page) showing each persons responsibilities – Describe under each role, what the responsibilities are and how they interact to make the service work.**

<b>Position</b>	<b>Responsible for:</b>
<b>Clinical Director</b>	
<b>Collection Medical / Facility Director</b>	
<b>Processing Medical / Facility Director</b>	
<b>Bone Marrow Collection Medical</b>	
<b>Quality Manager Clinical</b>	Clinical Quality Programme and ensuring integrated approach to Quality Management by working with the...
<b>Quality Manager Collection/Processing</b>	
<b>Transplant Physicians</b>	medical management of individual patients
<b>Matrons</b>	
<b>Ward Sisters</b>	
<b>Transplant Co-ordinator</b>	Coordination of Transplant Schedule
<b>Pharmacist</b>	
<b>Clinical Educator</b>	ongoing training and development of ...

## 5. Template Agenda For Monthly Quality Group Meeting

**DATE:**  
**WHERE:**  
**A G E N D A**

No.	Title	Notes
1.	Apologies for Absence	
2.	Minutes of Last Meeting	
3.	<b>Feedback:</b> Collection/Processing	
4.	Quality Manual Review	<i>Not on every agenda but only when needs to be discussed</i>
	Document Control Feedback	<i>This centre has a regular audit of document control and staff awareness</i>
	Document Development and Review (SOPs)	<i>The group will arrange for development and review of documents</i>
	Adverse Events, Deviations Lessons for Improved Care/ Reporting and Corrective Actions	
	Audit and Audit Timetable + collation of Evidence	
	Service Development Plan – update	
	Training and Education	
	Data Management	
	Clinical Trials	
5.	Any Other Business and Date Next Meeting to be held	

## 6. Template used to log Annual Record of educational Activity in SCT

Name (Consultant/BMT Coordinator/ Junior Doctor):	
Meetings Attended, (External/Internal)  (With Dates:)	
Courses Attended (External/Internal) includes Seminars, Conferences, Open Days, etc.  (With Dates:)	
Papers/Articles/ Posters Written/Presented:	
Other:	
Sign/Date	



## 7. Check-List for All SCT Nursing Staff Record Training & Competency/Supervised Procedure

### Method: Supervised Procedure

Supervisor signs to confirm competency of trainee. Trainee signs to confirm SOP has been read, understood and can follow procedure confidently.

**Trainee's Name:**.....

**Supervisor's Name:**.....

**Date:**.....

These SOP **MUST** be read after training and competency has been successfully assessed on IV infusion. However, nursing staff are encouraged to read these before and after training as booking in your training can take time.

This full list of SOPs to be completed within 3 months of starting work in the Transplant Unit.

SOP Number	Add SOP Version No.	SOP Title	Trainee to sign/date SOP, in order to confirm that SOP has been read		Supervisor to sign/date, only if trainee is found to be competent in following the SOP	
			Sign	Date	Sign	Date


Once completed please return to nurse **Clinical Practice Educator** for archiving.

**Method: Procedure**

Training and Competency Questionnaire. Please attach questionnaire with this record as evidence.

**Trainee's Name:**.....

**Supervisor's Name:**.....

**Date:**.....

This full list of SOPs to be completed within 3 months of joining.

SOP Number	SOP Version No.	SOP Title
------------	-----------------	-----------

SOP Number	SOP Version No.	SOP Title

Once completed please return to nurse **Clinical Practice Educator** for archiving.

**Other Training and Awareness**

Trainee's Name:.....  
Date:.....

Area	Date	Signature
Confirm you know where SOP Index, hardcopy SOPs & electronic SOPS can be found		
Confirm trained in IV Administration		
Confirm trained in Chemotherapy		
Confirm Trained in blood transfusion		
Confirm you know where Trust Policies & Procedures are kept for Health and Safety Policy Fire Safety Policy, Internal Disaster Recovery Plan, etc as those listed on the SOP index		
JACIE Awareness obtained from Quality Manger		
Awareness of the Operations/Procedures by the Lab Director		

Once completed return to nurse **Clinical Practice Educator** for archiving.

## **8. Example of an Education and Training for Junior Medical Staff**

*Refer to the FACT-JACIE Standards for the specific areas that must be covered.*

- Indications for transplantation
- Factors affecting the outcome of transplant
- Patient and donor selection and evaluation
- The HLA system
- Stem cell collection (bone marrow and blood)
- Conditioning regimens
- Immediate complications of transplant e.g. VOD, TTP, haemorrhagic cystitis
- Management of pancytopenia
- Management of neutropenic fever
- Management of graft versus host disease (GvHD)
- Management of respiratory disease (infectious and non-infectious)
- Management of viral disease
- Management of fungal disease
- Management of graft failure
- Management of late effects of transplant
- Monitoring minimal residual disease and chimerism
- Management of relapse
- Good clinical practice for clinical trials
- Procedures such as bone marrow harvesting are explained and taught according to the relevant SOPs.

## 9. Suggestions of Stem Cell Transplant Team Meets & their Frequency

<b>Time</b>	<b>Title</b>	<b>Purpose</b>	<b>Attendance</b>
Fortnightly	Quality Management	Discussion of quality issues, including errors, accidents and severe reactions, administrative issues, clinical governance	Representatives from Clinical, Collection and Laboratory Facilities including medical, nursing, scientific, managerial and data management staff. Chaired by Quality Manager
Weekly	Transplant Review Meeting	Discussion of all current in-patients	All SCT consultants, transplant co-ordinators, ward medical staff, ward nursing staff, support nurses, stem cell laboratory staff, data managers, HLA laboratory staff
Fortnightly	Planning meeting (alternates with unrelated search meeting)	Discussion of all forthcoming transplants	SCT consultants, transplant co-ordinators, asst transplant co-ordinator, support nurses
Fortnightly	Unrelated search meeting (alternates with planning meeting)	Discussion of all on-going searches	SCT consultants, transplant co-ordinators, asst transplant co-ordinator, support nurses, HLA laboratory staff
Weekly	Collection facility planning and outcome	Review past week's collections and planning of coming weeks collections	Collection facility director, Lab scientific director or delegate, OPD nursing staff

## ***Chapter 2: Document Development, Implementation, Control, Review & Archive***

*JACIE Standards: B/C/D4.4, B/C/D4.5, B/CM/C/D5*

### **Introduction**

Documents serve multiple purposes for the Quality Management Programme. Documents provide the structure needed for quality assurance through Policies and Procedures, ensure quality control using forms such as pre-printed orders and worksheets and substantiate Quality Management activities with audit reports, outcome analysis, training records etc. The Quality programme needs to identify documents critical to the Transplant Programme. These critical documents shall adhere to the document control system. The Transplant Programme needs to describe how the critical documents are conceived, generated, implemented, distributed, reviewed and stored.

Every part of the Transplant Programme requires written instructions on how to undertake key processes. All personnel in the facility should use these documents to carry out the tasks and they need to be sure that the document they are using is the current version. Documents (Policies, SOPs, Worksheets, Forms) are the foundation of the quality programme because they explain how each of the tasks undertaken, when grouped together, make the transplant programme run effectively. You will need to develop a procedure for writing, reviewing, implementing and controlling documentation (the “SOP about SOP’s”).

See the end of this chapter also for a list of required and suggested SOPs for each part of the transplant programme.

### **Standard Operating Procedures Manual**

The Transplant Programme shall maintain a Standard Operating Procedures Manual. The SOP Manual is the collection of policies and procedures containing written detailed instructions required to perform

procedures. The purpose of the SOP Manual is to maintain the policies and procedures in an organised fashion so that all current documents can be found. It can be an electronic Manual or a hard copy.

## **Developing the Documentation**

The first step in document development is to map out the transplant patient's journey from the time of referral to your institution through all of the different aspects of the process to discharge and follow-up. This sets the scene upon which you can develop documents.

You might already have some documents in place and they may only need to be updated or more information added. It also provides a way to find out which documents are already in place and where there are gaps.

Remember that you will need to ensure that everyone needs to provide input on the documents which are relevant to them (Clinical, Nursing, Pharmacy, Collection, Processing etc) to ensure that their responsibilities are clearly shown.

While the Quality Manager can facilitate drafting the SOPs, everyone must assume their responsibility in this process.



*Some Centres might have a group to start developing documentation i.e. Quality Management Group or Clinical Policy Group.*



*Some Centres have prepared a list of all existing documents and written procedures. This provides a good start because you might have a lot of the documents already in place, some of which may only need to be reviewed.*

## **Written agreements with third parties**

If the Transplant Programme interacts with third parties e.g. Collection or Processing, it must have policies and procedures for developing



written agreements. All such agreements should be dated, reviewed and renewed on regular basis similar to SOP's.

Note that this only refers to external services, not services that are part of the same institution.

### **Minimal elements required in each SOP**

Each individual procedure shall include the minimum requirements. The style and layout of documentation should be consistent for SOPs, Policies, forms and worksheets. The same Format/Style provides further evidence of standardisation and integration and should include:

- **A clearly written description of the objectives of the procedure** State what the procedure is intended to achieve e.g. safe infusion of cellular product.
- **A description of equipment and supplies used** Say what equipment etc. is required to undertake the procedure e.g. labels, syringes. **You can state “Not applicable” (N/A) if there is no equipment used.**
- **Acceptable end-points and range of expected results where applicable** State your centre's expected result e.g. after processing the number of CD34 cells should be at least  $2.5 \times 10^6/\text{kg}$ . The SOP should also include instructions on what should be done if the expected result is not achieved.
- **A stepwise description of the Procedure** Starting at point 1, list down each step the task requires until the end – during the steps you will identify any worksheets or forms used to support the task.
- **Reference to other SOPs or Policies** f a document e.g. 'Infusion of Cells SOP' states “step 4:“check identity of patient with product”, you might reference a policy called “Positive identification of Patients”. This might be an institution-wide.


- **Reference Section listing appropriate literature, if applicable** If you have used published articles, guidelines or data to support what you are doing then list these at the end of the document.
- **Documented Approval of each procedure and procedural modification** You have to have a system for document approval including approval date, signature of approving individuals and the effective date.  
A centre example is shown as a Document Matrix at the end of this section.
- **A copy of current versions of orders, worksheets, reports, labels and forms, where applicable** Copies of current versions, where applicable, must be a part of each SOP. The purpose is to assure that these documents are easily accessible to a reader of the SOP. Alternatively, they can be linked electronically to the SOP.
- Review of SOPs should include review of the associated labels, forms, worksheets etc.
- **Additional information** Some of the documents might require additional information; for example, age-specific issues, risks from undertaking the procedure, preventive and corrective action in the case of something which carries a risk e.g. use of a piece of equipment and so on.

## **Document Implementation**

All personnel within the Centre should follow the Standard Operating Procedures. In order for them to do this they need to be made aware of them.


There is no set way to make staff aware of documents – you might already have a system for communication in place. If you are a facility


who uses third parties for collection/processing then you need a system which ensures you are made aware of their document implementation as well as your own for documents that are relevant to your activities e.g. transport of products to the clinical unit.

 *Some centres have implemented a briefing system. They identify named individuals who are notified of all document issues and changes and these staff brief their colleagues in their work area. Some systems notify staff via communication books or staff meetings or other group meetings.*

### **Training & Educating Staff about Documentation**


The Transplant Programme need to have a system for documented review and training by staff members before he/she is allowed to perform new and revised policies and procedures. Documentation that staff have reviewed new and revised procedures and received appropriate training before the procedures are implemented is necessary must be in place.


 *In some centres, the SOP is issued to staff groups (i.e. Nursing for a Nursing SOP), for feedback BEFORE it is fully introduced. At the same time as it is being issued for feedback, a Training Needs Analysis is undertaken. A Training Needs Analysis is an audit of what Training may be required if any and by whom.*

 *Some Centres have Clinical Educators or Trainers whose role it is to ensure that staff receive training on the use of all Policies, Procedures, Worksheets and Forms. This training can take different forms e.g. observing someone doing the task accompanied by competent trained personnel or educational study days. Staff records should show clearly that they have been trained on procedures as required.*

## Access to Documents

The Standard Operating Procedures relevant to the processes being performed shall be readily available to the facility staff in their working environment. It might be a written copy or an electronic version of the SOP. Note that not **all** SOPs need to be available **everywhere**. See Standard B5.4.


 *Some Centres introduced Folders of Policies and SOPs. The folders follow the Transplant Pathway i.e. Section 1 of the Folder might be called “Patient and Donor Workup for Transplant”; Section 2 of the Folder might be called “Arrangement for Collection of Cells/Bone Marrow” etc.*


 *Some Centres moved paper-based documents onto electronic document management software so staff access documents via computer. Remember that a hard copy of everything needs to be kept somewhere accessible by staff in case of electrical failure.*

## Document Control

The purpose of document control is to make sure that only the currently approved document is available for use.

It includes a list of all documents critical to the Transplant Programme. These critical documents shall adhere to the document control system. The responsibility for document control rests with the Quality Manager in most Centres and this can be quite a challenge. Centres approach document control in different ways. All documents must be approved by the respective Director or Directors in cases where the documents overlap i.e. Clinical and Collection may have a document which covers both areas of responsibility. The author, reviewers and Quality Manager could also sign off the documents and in some cases, if you have a person responsible for Training then they could also approve and sign.

 *In some hospitals, the documents must be formally approved by for example the Hospital General Director. **Check whether anybody outside of the Transplant Programme needs to be aware of your documentation system and requirements.***

 *Some institutions have Guideline Review Committees whose role is to look at the process for development of the documentation e.g. have all the steps below been followed?*


**The things that you must do in order to control documents are:**


- Make sure each document has a **unique number, alphanumeric reference or code.**
- Make sure each document has a **Unique Title** to reflect what it is about.
- Make sure each document has a **Version Number** and change this whenever the document is amended or changed in any way.
- Show clearly on the document the **Issue Date** i.e. the date you provide it for use to all personnel within the facility.
- Make sure each document has a specific **Review Date** i.e. the date upon which you and your colleagues will look through the document to establish whether it is still relevant to the tasks being undertaken. Even if there are no changes required the Director should approve the review of the document and then it will continue to be a “live” document. You will not need to issue a new version but you will need to document the review and to give it a new review date. You may need to review a document earlier than the review date if there has been a problem or if an immediate change is required i.e. “change to drug dose”. When a document is reviewed and changed, you will need to give it a new review date and version number and make sure you get the document signed as approved. Staff need to be made aware of the reviewed document.

It can be helpful to:

- Make sure that the **authors name is written on the document.** This will help staff to see who wrote the document and who to contact if there is anything wrong with it.
- **State the Number of Pages the document has** e.g. page 1 of 18 so that no pages get missed or become lost and if this happens, you can easily identify which pages they are.
- If you are attaching a **Form or Worksheet to an SOP**, you could attach an **Example of a completed one** to show how it should appear.

You should **develop an SOP for Document Control (See Example Template at end of this section)** which includes all of the above. You should advise staff of the process to follow if they cannot understand the document or if they see an error in the document. Control of issue of documents ensures that Centres know where documents are located so that when changes are made, recall is done on every document.

 *Some Centres have paper-based systems with documents contained in folders. These documents all carry the unique reference, issue date, review date and issue number etc. as described above.*

 *Some centres now use electronic document storage and there are websites available which show software you can buy which does a lot of the above for you but remember, you need to ensure that you have a backup in case of computer system failure – this might be in the form of paper copies in a master file. For signature and approval purposes most centres will keep a paper master file in case of problems. Keep a master file of staff members' signatures and initials.*

## **Document Review**

The document requirements above have briefly described what is required for document review.

A document may need to be reviewed earlier than the date you have set because conditions require, but every document must be reviewed at least every two years as per the JACIE Standards.

- A document review must include the personnel who wrote the document, the relevant Director and can also include staff from the ward or department areas that perform the tasks.
- The revised document should be given a new review date and version number.
- The revised document must be signed and dated when finally approved (see above).

**Even if the documents do not require any changes they should still be approved for continued use.**


Review of SOPs should include review of applicable copies of current versions of orders, worksheets, reports, labels and forms.


### **Archived or Obsolete Documents**

Archiving documentation is an important element of the quality management programme. Documentation is important for the investigation of errors, complaints etc.

All documents must be archived for a minimum of 10 years. This includes all old versions of documents and those which you no longer use at all (Obsolete).


Pay attention to any legal requirements in your country regarding minimum archiving periods.

 *Some centres keep a paper register of all documents in a book whilst others keep this information electronically. You must keep a central register of all current “in use” and “Archived” or “Obsolete” documentation.*

 *Some centres store archived documents on disks or in files. Alternatively document control software as described above can be used to archive documents.*

### **Recall**

When a new or revised document is issued, the old version **MUST** be recalled so that there are no duplicate copies in existence (except as an archive under the control of the Quality Manager).

 *Where documents are electronically stored and used, this process is easy because the new version is placed on the electronic system and the old version is archived automatically. Where documents are paper-based, this can be more difficult depending upon the number of folders of documents you have and where these are held. Some Institutions issue a recall letter whilst others manually collect old versions (easier if you are in one location).*

### **Institutional Documents**

Some of the documents within the Centre will probably be Institutional Policies and thus are outside of your immediate control. The JACIE standards require that these documents be reviewed by the Programme Director at least every two years to establish any direct impact on the programme. For instance, the Hand Washing Policy probably relates to the entire institution and your Institutional Board is responsible for ensuring its review. However, because this policy affects your transplant programme you will need to ensure it meets your specific needs, and so this policy and others like it should still form part of the document review.


### **Deviations from Policy or Procedure**

See Example Template at end of this Section

Deviations from key policies and SOPs means not undertaking the tasks as you have written and agreed them. Deviations like this need to be documented and approved by the relevant



Clinical/Collection/Processing Director in advance of them occurring whenever possible (planned deviations). If a deviation occurs that was not planned then the relevant Director must document that he is aware of the deviation and any actions undertaken.

 *To address this measure, some centres have linked recording of deviations into their Incident Reporting system and use the same forms for both.*

- *Some centres are addressing the issue of deviations through their Quality Groups and other similar meetings.*
- *Where Centres use worksheets and forms as part of the Transplant Process the forms are being amended so that deviations can be recorded as and when they take place.*
- *One centre example uses an existing system of Near Miss reporting to document deviations rather than having a separate form. The system “Lessons for Improved Care” (which is described under Adverse Event Reporting) is a simple form which asks – “What Happened”, “What Immediate Action Was Taken” and “What could be done to prevent it happening again”. The form asks for a “Category” and “deviation” is one of the categories.*

In the centre concerned, the Category is shown as “Deviation from ....” An example was Cyclosporin testing. The SOP stated the frequency of testing however, a small sample of patients were tested more frequently for a period in order to establish whether any benefit from additional testing would be found. This was a “deviation” from the SOP – it was agreed in advance. Details were filled in on the Lessons for Improved Care Form and this was signed off by the Programme Director. In the same way, if the deviation had not been planned, the same form would be completed. The forms are reviewed at least monthly by the Programme Director, Quality Manager, Matron, Clinical Director and others as appropriate. The forms are also discussed and corrective actions agreed at the Quality Management Group Meetings.



## **Some Examples of Common Deficiencies Noted**

*Evidence must be provided that the Quality Manager (QM) reviews all policies and procedures.*

*The Inspector comments that critical end points must be defined in SOPs. This means that there must be a regular review of important outcome Standards e.g. transplant related mortality, line infection rates etc. The results of this analysis should be compared to pre-defined definitions of what is acceptable. The centre must develop a plan for review of outcomes and define the range of what is acceptable and actions to be taken in case of deviation.*

*The Inspectors did not locate a SOP on describing the procedure, purpose for implementation and reviewing of SOPs. A SOP about SOPs will need to be written.*

*There were no written policies for the nursing staff.*

*Policies and Procedures are not reviewed/revised every two years. An SOP should be established for biannual review.*

*SOPs were often not associated with examples of completed forms or labels. The centre needs to ensure that completed forms or labels are appended or linked to all SOPs where relevant.*

*The Inspector noted that there was no SOP for validation/qualification of a new procedure/equipment/reagent.*

*Some SOPs were overdue for review. A small number were obsolete. Obsolete and superseded SOPs should be removed from the manual.*

### Example Templates Provided For This Section

<b>Number:</b>	<b>Title:</b>
1.	Example of the Procedure for Document Control
2.	Approval and Issue of Documentation <i>Pro Formas</i>
3.	Example Template for Reporting Deviations and Near Misses

## 1. Template For Procedure For Document Control

<b>Document Title</b>	<b>Document Development and Control Policy</b>
<b>Reference or Code:</b>	<b>Author:</b>
<b>Approved by:</b>	<b>Validated:</b>
<ul style="list-style-type: none"> <li>• <b>Objectives</b> – say what the document is going to achieve</li> <li>• <b>Purpose</b> – why is document being written i.e. to ensure documents are controlled etc.</li> <li>• <b>Scope</b> – Is the document Clinical only or does it being implemented wider i.e. Collection/Processing</li> <li>• <b>Equipment and Supplies Used</b> – are there any? if not put N/A</li> <li>• <b>Personnel and Responsibilities</b> – Who is responsible</li> <li>• <b>Definitions</b> or Glossary of Terms</li> <li>• <b>Procedure</b> – What is the Process for writing, approving, implementing, reviewing, communicating and archiving documentation:-</li> <li>• <b>Writing the Document</b></li> <li>• <b>document style and What MUST be included</b> - Say what each document must contain</li> <li>• <b>Document Approval Process</b> – Who by and when?</li> <li>• <b>Briefing of Documents</b> – How do you advise staff?</li> <li>• <b>Viewing Documents</b> – How do staff SEE documents</li> <li>• <b>Process for Printing Documents</b> – Are staff permitted to print documents?</li> <li>• <b>Process for changes to documents and</b></li> <li>• <b>Document review</b> – How, When and by Whom?</li> <li>• <b>Issue of Approved Documents</b> – How, When and By Whom?</li> <li>• <b>How are Documents Recalled</b> when out of date?</li> </ul>	
<b>Issue Date</b>	<b>Issued BY</b>
<b>Review Date</b>	<b>Reviewed By</b>
<b>Page 1 of 1</b>	<b>Date Approved</b>

**2. Example template  
APPROVAL/ISSUE OF DOCUMENTATION**

<b>DOCUMENT TITLE</b>				
<b>TYPE OF DOCUMENT</b>		<b>TICK WHICH IT IS</b>		
<b>POLICY</b>				
<b>SOP</b>				
<b>TRAINING &amp; EDUCATIONAL ASSESSMENT FORM</b>				
<b>DOCUMENT STATUS</b>	<b>EFFECTIVE DATE</b>		<b>REVIEW DATE</b>	
<b>NEW DOCUMENT APPROVED</b>	when is it "live"		when will document be reviewed again?	
<b>AMENDED DOCUMENT APPROVED</b>	“		“	
<b>REMOVE THIS DOCUMENT AND ARCHIVE</b>	“		“	
<b>KEY CHANGES</b>	<b>WHERE IN DOCUMENT</b>		<b>ACKNOWLEDGED</b>	
<b>Drug xxxx Dose Change for YYY</b>	Page x Paragraph y etc.		By relevant Director	
<b>NAME (print)</b>	<b>Signature</b>		<b>Title</b>	<b>Date</b>
Relevant Director				

**3. Example Template – Form to Record Deviations and Near Misses**

**LESSONS FOR IMPROVED CARE SYSTEM**

**Clinical Area:**

**Category:**

**Time:**

**Date:**

**Was there a Deviation from any Policy and/or Standard Operating Procedure**  
**YES/NO**

**What is the Title of the Policy and/or Standard Operating Procedure Deviated from:**

\_\_\_\_\_

**Job Role of person completing form:** \_\_\_\_\_

**What Happened?**

\_\_\_\_\_

**What Immediate Action Was Taken?**

\_\_\_\_\_

**What Could Be Changed to Prevent Reoccurrence?**

\_\_\_\_\_

**Complete on reverse of form or separate sheet if necessary**

**Was any other type of Incident Form Completed?**

**Incident Reference No.**

**Sign off by:**

## **List of Policies and Standard Operational Procedures (SOPs) for Cell Collection, Processing and Transplantation Programmes**

### **Format of SOPs**

There must be an SOP covering the procedure of preparing, implementing and revising all procedures and an SOP for document control; these may be combined in a single SOP. Other elements that must be included are:

- A procedure for preparation, approval, implementation, review, revision, and archival of all policies and procedures.
- A standardized format for policies and procedures, including worksheets, reports, and forms.
- A system of numbering and titling of individual procedures, policies, worksheets, and forms.

(B/C/D 5.3) Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual procedure shall include:

1. A clearly written description of the objectives.
2. A description of equipment and supplies used.
3. Acceptable end-points and the range of expected results, where applicable.
4. A stepwise description of the procedure, including diagrams and tables as needed.
5. Reference to other Standard Operating Procedures or policies required to perform the procedure.
6. A reference section listing appropriate literature, if applicable.
7. Documented approval of each procedure by the ... Director or designated physician prior to implementation and every two years thereafter.
8. Documented approval of each procedural modification by the ... Director or designated physician prior to implementation.
9. A copy of current version of orders, worksheets, reports, labels, and forms, where applicable.

## List of SOPS

The JACIE Standards do not prescribe the number nor the type of SOPS that a programme should have since this will depend on the size, organisation and complexity of the programme. However, the Standards clearly define the areas that must be addressed in written policies and procedures as follows:

*B/CM/C/D5 The Programme must have written policies and procedures addressing all appropriate aspects of the operation including, but not limited to:*

<b>Part B: Clinical</b>	<b>Part C: Cell Collection (incl. BM)</b>	<b>Part D: Cell Processing</b>
<ul style="list-style-type: none"> <li>• Donor and recipient evaluation, selection, and treatment.</li> <li>• Donor and recipient consent.</li> <li>• Donor and recipient confidentiality.</li> <li>• Infection prevention and control.</li> <li>• Administration of the preparative regimen.</li> <li>• Administration of HPC and other cellular</li> </ul>	<ul style="list-style-type: none"> <li>• Donor and recipient confidentiality</li> <li>• Donor consent</li> <li>• Donor treatment</li> <li>• Donor screening, testing, and eligibility determination</li> <li>• Management of donors, including pediatric donors if applicable</li> <li>• Product collection</li> <li>• Labeling (including</li> </ul>	<ul style="list-style-type: none"> <li>• Donor and recipient confidentiality.</li> <li>• Product receipt.</li> <li>• Processing and process control.</li> <li>• Prevention of mix-ups and cross-contamination.</li> <li>• Red cell compatibility testing and processing of ABO-incompatible products to include a description of the indication for and processing methods to be used for red cell and plasma depletion.</li> </ul>



<b>Part B: Clinical</b>	<b>Part C: Cell Collection (incl. BM)</b>	<b>Part D: Cell Processing</b>
<p>therapy products, including exceptional release.</p> <ul style="list-style-type: none"> <li>• Administration of blood products.</li> <li>• Facility management and monitoring.</li> <li>• Disposal of medical and biohazard waste.</li> <li>• Emergency and disaster plan, including the Clinical Program response.</li> </ul>	<p>associated forms and samples)</p> <ul style="list-style-type: none"> <li>• Product expiration dates</li> <li>• Product storage</li> <li>• Release and exceptional release</li> <li>• Transportation and shipping to include methods and conditions to be used for distribution to external facilities</li> <li>• Critical equipment, reagent, and supply management</li> <li>• Equipment, operation, maintenance, and monitoring to include corrective actions in the</li> </ul>	<ul style="list-style-type: none"> <li>• Cryopreservation and thawing.</li> <li>• Labeling (including labeling of associated forms and samples).</li> <li>• Product expiration dates.</li> <li>• Product storage to include alternative storage if the primary storage device fails.</li> <li>• Release and exceptional release.</li> <li>• Cellular therapy product recall to include a description of responsibilities and actions to be taken, including notification of appropriate regulatory agencies.</li> <li>• Transportation and shipping, including methods and conditions within the Processing Facility and to and</li> </ul>

<b>Part B: Clinical</b>	<b>Part C: Cell Collection (incl. BM)</b>	<b>Part D: Cell Processing</b>
	<p>event of failure</p> <ul style="list-style-type: none"> <li>• Cleaning and sanitation procedures to include identification of the individuals responsible for the activities</li> <li>• Disposal of medical and biohazard waste</li> <li>• Facility management and monitoring</li> <li>• Emergency and disaster plan, including the Collection Facility response</li> </ul>	<p>from external facilities.</p> <ul style="list-style-type: none"> <li>• Product disposal.</li> <li>• Reagent and supply management.</li> <li>• Equipment operation, maintenance, and monitoring, to include corrective actions in the event of failure.</li> <li>• Cleaning and sanitation procedures to include identification of the individuals responsible for the activities.</li> <li>• Environmental control to include a description of environmental monitoring plan.</li> <li>• Hygiene and use of personal protective attire.</li> <li>• Infection control, biosafety, and chemical and radiological safety.</li> </ul>

Part B: Clinical	Part C: Cell Collection (incl. BM)	Part D: Cell Processing
		<ul style="list-style-type: none"> <li>• Facility management.</li> <li>• Decontamination and disposal of medical and biohazard waste to include Processing Facility-specific requirements where these differ from institutional requirements.</li> <li>• Emergency and disaster plan, including the Processing Facility response.</li> </ul>

### Suggested SOPs

Based on JACIE training courses and experience gained from JACIE inspections undertaken to date, the following is a list of SOPs that should be considered for inclusion. While this list does **not** attempt to be all-encompassing and will depend on how a programme is organised, it may prove to be useful as an *aide memoire* when preparing your procedures.

On a general note, JACIE will recognise that Stem Cell Transplantation is not an activity that occurs in isolation, and, in many health service providers/hospitals, there may already be a generic written documents in place covering e.g. emergency, health and safety, medical waste disposal, disaster response etc that will suffice if referred to in some of the central SCT documents such as the Quality Plan/Manual.

**General system SOP's / overall SOP's**  
**(could apply to Clinical Programme, Collection and Processing Facilities)**

- System of generating, reviewing, implementing and revising SOPs and document control (format of SOP's, document code and version number, writing, validation, training, authorisation, distribution, archiving, revision, locations, responsibilities)
- System of internal auditing (planning, performance, reporting, corrective actions, evaluation)
- System for managing errors, incidents and adverse reactions (detecting, evaluating, documenting reviewing and reporting to patient's physician and/or external agency)
- Training / education system of personnel (nurses, technicians, physicians, staff, fellows, administration, dieticians, new employees, etc.; annual plan, continuous education, transmission of knowledge, literature, training records, etc.)
- Safety requirements (staff health and safety, patients risks, annual safety training of staff)
- Environmental requirements
- Material supply
- Equipment control / maintenance
- Storage of drugs / reagents /supplies
- Data management / reports
- Management of patients in clinical trials
- Outcome review (e.g. transplant-related mortality, apheresis data, engraftment)
- Service level agreements with other facilities, e.g. external collection/processing facilities, donor registries
- Disaster response

## **Clinical Facility**

- General
  - i. Chemotherapy administration (prescription, checking etc)
  - ii. Blood product administration
- Assessment of patient
  - i. Documentation of diagnosis and indications for transplant
  - ii. Patient information and consent
  - iii. Pre-transplant workup
  - iv. Fertility management
- Selection and Assessment of donor
  - i. Criteria for donor selection (including procedure if donor does not fulfil criteria)
  - ii. Unrelated donor search
  - iii. Donor information and consent
  - iv. Pre-donation workup (incl. history, questionnaire (family history, travel history, transfusion history), laboratory tests)
- Transplant protocols
  - i. Conditioning regimens
  - ii. Safe administration of high dose therapy (chemotherapy and radiotherapy)
  - iii. Reinfusion of HPC (Cryopreserved and non-cryopreserved)
  - iv. Management of major ABO incompatibility
  - v. Graft versus host disease prophylaxis
  - vi. Infection prophylaxis and surveillance
- Supportive care
  - i. Isolation & antimicrobial procedures
  - ii. Nutrition
  - iii. Blood product support
  - iv. Management of central lines
  - v. Mouth care
- Complications

- i. Infection management (may be more than one SOP)
- ii. CMV reactivation /disease
- iii. Acute graft versus host disease management
- iv. Chronic graft versus host disease management
- v. Delayed engraftment
- vi. Other complications (VOD, TTP, Haemorrhagic cystitis)
- vii. Transfer to ITU
- viii. Terminal care
- ix. BMT Mortality and Morbidity
- Post-transplant care
  - i. Discharge
  - ii. Shared care, if applicable
  - iii. Post-transplant infection prophylaxis
  - iv. Out-patient monitoring
  - v. Policy for revaccination
  - vi. Follow-up for long term complications
  - vii. Minimal residual disease monitoring
  - viii. Chimerism monitoring
  - ix. Use of DLI
- Data collection
  - i. Procedure
  - ii. Consent for reporting to registries
  - iii. Review of outcome data on a regular basis
- Documentation and reporting of incidents and adverse events (AE) (see above)
- Management of patients in clinical trials

### **Collection Facility**

1. Donor evaluation and care
2. Selection and Assessment of donor; if not performed by clinical programme (see above)
3. Pre-donation workup; if not performed by clinical programme (see above)

4. Donor information and consent
5. Evaluation of donor immediately prior to collection
6. Care of donor during and after collection (including policy for blood product administration)
7. Donor follow-up
8. Documentation and reporting of incidents and AEs (see above)
9. Equipment / Instruments /Reagents
10. Maintenance
11. Storage
12. Validation
13. Cell collection
14. Arranging and ordering collection (including written order)
15. Mobilisation regimes and criteria for starting PBSC collection
16. Apheresis procedure (including target cell numbers)
17. BM harvest procedure (including target cell numbers)
18. Identification and labelling of product
19. Transport of product to processing facility
20. Storage of product if applicable
21. Policy for review of records
22. Environmental monitoring

### **Processing Facility**

1. General
  - i. Staff training
  - ii. Laboratory Safety
  - iii. Maintenance
  - iv. Environmental monitoring
  - v. Validation of equipment and methods
  - vi. Quality control testing of products and reagents
2. Data management
  - i. Booking in and receipt of harvests
  - ii. Process and results validation and reporting
  - iii. Database entry and report generation
  - iv. Data storage and archiving
3. Procedures
  - i. CD34 count

- ii. Buffy coat preparation
- iii. Red cell depletion
- iv. Plasma depletion
- v. CD34 selection
- vi. Other manipulation
- vii. Viability testing
- viii. Microbiological screening
- ix. Other
4. Labelling
5. Cryopreservation
6. Storage
7. Thawing procedure
8. Transport (including temperature monitoring, where applicable)
9. Policy for disposal
10. Internal audit
11. Policy for outcome review (engraftment)



## ***Chapter 3: Errors, Accidents, Adverse Events, Biological Product Deviations & Complaints***

*JACIE Standards: B/C/D4.10*

### **Introduction**

A very important part of the Quality Programme is the development of a robust system for reporting, investigating and resolving all errors, accidents, adverse events, biological product deviations and complaints.

Some of the terms above are used to describe transplant safety and the basic principles to follow at the time. Reporting and reviewing of the above should not be about “blaming” individuals because it is usually the “process” which is at fault and not any single person. All personnel should be encouraged to report anything which affects transplant safety.

Prevention of errors is one of the most important aspects of safety in transplantation. Analysis of potential risk factors associated with the entire range of procedures should form part of the overall transplant programme development. Ideally, every document should be analysed and potential risk factors identified BEFORE they are implemented so that the level of risk can be determined i.e. is there a serious chance of harm to patient/staff as a result of the steps required in the procedure? Documentation is important for investigation of errors, accidents and adverse events, biological product deviations and complaints because these investigations are frequently retrospective. If outcomes change over time, you need to be able to go back to previous versions of your Policies, Procedures and Forms (See Chapter 2) to determine if an operational change was the cause.

Generally, you should know where errors occur in the processes and why they occur. You should then be familiar with how to deal with errors, e.g. do you use a Near Miss Reporting System (Prevention of Errors) and a Corrective Actions System when Incidents have happened?

## Definitions of What to Report

**Adverse Reaction/Serious Adverse Events (SAE)** – Any untoward occurrence associated with the procurement, testing, processing, storage, distribution and application of tissues and cells which might lead to transmission of communicable disease, death or life-threatening, disabling or incapacitating conditions for patients or which might result in or prolong hospitalization or morbidity<sup>2</sup>.

**Near Miss** – An event which, if not identified in time, would have led to an Error, Accident or Adverse Reaction or SAE.

**Biological Product Deviation (BPD)** – Any event associated with the manufacturing of a cellular therapy product, including testing, processing, packing, labelling, or storage, or with the holding for distribution, of a licensed biological product, if that event meets the following criteria:

Either:

- Represents a deviation from current good manufacturing practice (or current good tissue practices), applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or
- Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and:
  - Occurs in your facility or another facility under contract with you; and
  - Involves a distributed biological product<sup>3</sup>.

## Investigation and Reporting

Most institutions should have a Risk Management and/or Health and Safety Department with policies which provide information on the types of general events to report. Most institutions should have Risk

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<sup>2</sup> Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004

<sup>3</sup> Definition from FACT-JACIE Accreditation Manual, 5th ed.

Assessment Policies in place with regular Risk Assessments being undertaken and Risk Registers kept within Departments. Many institutions have mandatory audit requirements – Moving & Handling, Hand Washing, Work Area, Fire, Major Accident Policy, etc.


The relevant Director is responsible for review of all Transplant related incidents within the Programme. However relevant higher regulatory bodies (e.g. Institutional Management) will usually become involved depending upon the nature of the incident being investigated.

The Risk Register will determine the likelihood of risk associated with the procedures carried out by the department concerned. To formulate a proper risk register requires that every procedure is written down to identify where potential risks might be within that procedure:





*A centre **example** might be the Procedure for ABO Incompatible Blood or Blood Products – the risk is the serious disability or death of a patient as a result of haemolytic reaction resulting from administration of such a product. Within the procedure you should state the likelihood of the risk occurring and the likely severity of the outcome if it does occur. If there is a “near miss” with such a product, you might complete a Near Miss Incident Form to document that if intervention had not occurred, a more serious incident would have taken place. In this event, the centre would investigate fully in collaboration with other areas e.g. Blood Bank, staff involved and a written report describing what has been done to avoid a similar problem happening would be produced. The procedure itself might require change and staff might require some further training – all of this should be documented. If the actual incident did result in serious disability or death of the patient, there would be completion of the required institutional documentation and a full investigation of the problem, the equipment/procedures followed, dates of corrective actions and evidence of training/re-training. In both instances you would need to provide evidence that audits of new procedures have been repeated to ensure corrective actions have been properly implemented and are being adhered to. In the event of very serious outcome, there would be reporting mechanisms in place for ensuring*

*that the appropriate authorities and agencies are advised. Quality Managers should liaise closely with their Institution's Health and Safety/Risk Management teams – in some centres Quality Group membership includes members of these departments. See Example 1 Types of incident reported.*

 *A **further example** might be the malfunction of equipment e.g. Apheresis Machine. Facilities should have clear instructions and provide adequate training in the use of such equipment and this should be fully documented. Only trained personnel should be using such equipment. If there was an incident with equipment, the Institution would be expected to provide full service and maintenance history of the equipment and validation documentation which should provide evidence that the machine is regularly calibrated and performs as set out in the manufacturers specifications at all times. See Chapter 4 for Validation Example. Validation of equipment and supplies to ensure their consistent performance should form part of a regular timetable of audit.*

Your institution might already have a reporting system in place. If it does, then you might not be able to implement anything else but you must comply with JACIE quality Standards by having a system in place which allows you to obtain the reports as they are generated so that the relevant Director can review them.

 *Many centres have set up a complementary system for “near miss” reporting and this works by the completion of a special form which is filled in and submitted to the Quality Manager and relevant Director. The aim of “near miss” reporting is not to blame the individual but to prevent an error or accident in the future by adjusting the quality programme accordingly.*

 *A centre example involved the setting up of a system called Lessons for Improved Care. See Example 2 Form to report deviations and near*

*misses at end of this Section. This system is a means of quickly recording near misses as they occur. All staff are responsible for completing the forms which ask 3 simple questions – What Happened, What Immediate Action was Taken and What Might be Done to Prevent Recurrence of the Problem. Each near miss is Categorised i.e. – Blood Products, Sampling, Transport, Labelling, Infusion, Nursing, Medical, Drugs, Pharmacy, Result Processing. Every day, reports are collected and on a weekly basis, the relevant Director, Quality Manager, Head Nurse and Pharmacy or other services as required review the documents and discuss corrective actions. Sometimes, there might be a need for a more thorough investigation and this would involve observations, interviews and complete review of the procedures which linked to the near miss which took place. The results and outcomes are reported back to all departments within the Programme and monthly “Trend” reports are written to establish whether improvements have been made and are working. Whatever corrective action is taken e.g. amending an SOP or re-training staff, all of this is documented and audited for improvement.*




*As explained above, many centres have mandatory Institutional Incident Reporting Systems in place and it might not be possible or desirable for you to set up your own system. Even in centres where there is a system such as the one described above, there is still a need for Quality Managers to be able to obtain copies of the Institutional Incident Forms Completed where they are related to events which have occurred within any part of the Transplant Process (Clinical, Collection and Processing). In some centres, Quality Managers have arranged for copies of completed Institutional Incident Forms to be sent to them directly and some are able to download the reports from the Institutions Incident Database (where these exist). By obtaining copies, you are able to ensure that everything which occurs within the Transplant Programme is being reviewed by the relevant Directors and corrective action is being taken as per the Standards.*

Detection and reporting of errors, accidents and adverse events is the responsibility of every employee as an increasingly important aspect of quality is safety.


## **Complaints**

Many institutions have an Institution-wide Complaints Policy in place and again, your facility will be expected to follow Institutional requirements. If there is not a policy in place, then one should be developed and implemented. See Example 3 *SOP Adverse Event & Near Miss Reporting*.

 *In some Institutions, the Chief Nurse within the Department receives all Complaints e.g. all complaints relating to Haematology and some but not all of these might be Transplant related. Some centres have set up complementary systems with specific forms for the recording of Transplant related issues. These complaints are investigated and reported as described below. Whatever method exists for receiving and dealing with complaints within your institution, as the Quality Manager, you will need to obtain copies and be made aware of investigations and corrective actions which are being put into place. Some Quality Management Groups have Complaints as a regular agenda item.*

**Investigation, Analysis & Corrective Action** – Action taken as a result of adverse event to prevent recurrence.

Whilst there is no set timeline for investigation, review and analysis, this should be undertaken quickly so that a potential repeat of the issue is avoided.

 *Investigation and analysis in some centres is done through formal review of the entire procedure to identify where the fault occurred. Collection and Processing facilities have Quality Incident Reporting mechanisms in place and these are shared with the Clinical Programme where an incident occurred across the linked process e.g.*

*transportation of product from collection/processing facility to clinical facility: all parties receive the Quality Incident Report and meet to analyse and close the incident – the investigation itself might involve looking at all documentation, training records, having discussions with staff involved and actually observing the process as it happens.*

*The forms, complaints etc. can be categorised by type e.g. department, procedure (e.g. Cell Reinfusion) and equipment used and the forms then evaluated. This evaluation can be done by specific groups or as part of one of the regular meetings i.e. Quality Group. The more frequent events should be prioritised and then resolve: this can be done by amending policies and procedures, implementing revised worksheets or re-training staff. By doing this, the quality programme is continuously being improved.*



*Examples in some centres include; weekly review with relevant Director, Quality Manager, Chief Nurse and/or Medical Director and area where incidents occurred. Some Centre Quality Group Meetings have Errors, accidents and adverse events as part of the rolling agenda (as described above); group members should include all related facilities. Some centres have separate Risk Management Groups.*


**It is everyone's responsibility to report anything which affects the safety of transplantation.**

### **Biological Product Deviations (BPD) (See definition above)**


The most common BPD's encountered by Clinical Programmes involve products with Positive Microbial Cultures or products from ineligible donors. Such products are only used by Clinical Programmes when an evaluation shows that the benefits outweigh the risk to patient and no alternative is available.

In some cases the relevant information is not known until after the infusion has occurred. Centres are responsible for deciding on whether they will use these products and if so, under what circumstances. There must be a detailed plan and procedures in place which describe:

- Whether a product with Positive Microbial Culture can be use
- In what Circumstances its use would be permitted
- How is the recipient protected
- How full records about all aspects of the process are kept.


 For *methods for investigation and review where the BPD was unknown until AFTER the cellular product was infused, centres can also follow the processes above.*

*Investigation and analysis in some centres is done through formal review of the entire procedure to identify where the contamination might have come from. Collection and Processing facilities have Quality Incident Reporting mechanisms in place and these are shared with the Clinical Programme where an incident occurred across the linked process. All parties receive the Quality Incident Report and meet to analyse and close the incident – the investigation itself might involve looking at all documentation, training records, having discussions with staff involved and actually observing the process as it happens.*

 BPD Where it was known **BEFORE** product Infused – The Problem was “Positive Microbial Culture in Stem Cell Donation”  
*Methods for investigation and review where the BPD was known **BEFORE** cellular product was infused followed the systems described above. A product from an unrelated donor was potentially contaminated due to infection of the donor with a tropical disease, and the Collection Centre only advised the Transplant Centre on the morning of the Collection. In the meantime at the Transplant Centre, the recipient was fully conditioned using full intensity conditioning regimens. The reasons behind the potential contamination were fully investigated and revised processes put into place at the Collection Facility following close liaison with the Clinical Facility. The Centre had no alternative but to use the product as no other donor was available in time. The Centre quickly liaised with specialists at their own centre and external specialists in tropical diseases, and several*



*different samples were sent to different laboratories and results returned within a couple of hours prior to cell infusion. All steps were taken to safeguard the recipient (prophylaxis), and the recipient was informed of what was happening at all stages both prior to, during and after infusion. The cells turned out to be free of contamination but valuable lessons were learned and procedures revised at the Collection Centre to avoid future problems of this type. Records of the entire process were kept in patient case-notes, incident reports, deviations and near miss reporting with corrective actions clearly shown.*

 *The centre where the BPD occurred BEFORE infusion holds weekly Incident Review meetings with relevant Directors, Quality Manager, Chief Nurse and/or Medical Director and area where incidents occurred. The Quality Group Meeting at this centre has errors, accidents and adverse events as part of the fixed agenda (as described above) and group members include all related facilities. Some centres have separate Risk Management Groups Centres have worked with all related facilities to develop procedures including how products are managed and reported in accordance with applicable regulations. Policies are in place which cover disposal of product, criteria for release, labelling, notification of recipient, investigation of cause, timely notification of transplant physician and other related facilities involved. Procedures are in place for dealing with BPD if unknown until infusion has occurred as per JACIE Standards.*

A sheet which gives examples of the types of Incidents Reported is shown in Example 1 – This is not a definitive list and must not be used as the only items to report.



## **Some Examples of Common Deficiencies Noted**

*Procedures for cell collection are good but there is lack of document which specifies that the procedures are validated.*

*Communication between collection facility and clinical programme needs to be more formal. Adverse events were reported and investigated within the processing service quality programme but there was no SOP for reporting this to the Clinical Programme. An SOP should be created.*

*The maintenance of equipment is not consequently registered in the logs. Maintenance of equipment should be recorded. Standard pro formas could be used for each piece of equipment.*

*An SOP for maintenance of re-agent refrigerators was missing.*

*Documentation containing instructions for infusion does not list indications and contra-indications or side-effects and hazards. This document should be revised as necessary.*

*It was identified that some donors leave the facility after collection of bone marrow without seeing any member of the centre team. There must be an SOP for donor review prior to discharge.*

*There are procedures for biological, chemical and radiation safety. The personnel in the Centre are not familiar with these procedures. There must be a system for monitoring the training and competencies of these procedures and the system for this must be outlined in an SOP or in the safety manual*

### Example Templates Provided For This Section

<b>Number:</b>	<b>Title:</b>
1.	Types of Incident Reported
2.	Form to report deviations and near misses
3.	Registration Form for recording Complaints, Adverse Events and Near Misses
4.	Example of an Allogeneic Day Case Inpatient <i>Pro forma</i>
5.	SOP Adverse Event & Near Miss Reporting

## Example 1

*NOTE: This is not a definitive list and must not be used as the only items to report*

<b>TYPES OF INCIDENT REPORTED</b>	
<b>Category</b>	<b>Details</b>
Medication Errors	
ABO Incompatible Blood Products	
Malfunction/Misuse of Equipment	
Contaminated drugs, devices or products provided by facilities	
Labelling of Products	
Samples missing or delivered to wrong laboratory	
Results not provided in adequate time	
Signing of drug charts	
Verification of cytotoxic drugs	
Bag damage during thawing of cellular product	
Deviations from Policy or Procedure if unplanned	
Severe reaction during Infusion of cellular product	
Transport issues	
Product found to have Positive Microbial Culture	
Failed Engraftment	

**EXAMPLE TEMPLATE 2**  
**FORM TO REPORT DEVIATIONS AND NEAR MISSES**

**LESSONS FOR IMPROVED CARE SYSTEM**

**Clinical Area:**

**Category:**

**Time:**

**Date:**

**Was there a Deviation from any Policy and/or Standard Operating Procedure**  
**YES/NO**

**What is the Title of the Policy and/or Standard Operating Procedure Deviated from:**

\_\_\_\_\_

**Job/Role of person completing form:** \_\_\_\_\_

**What Happened?**

\_\_\_\_\_

**What Immediate Action Was Taken?**

\_\_\_\_\_

**What Could Be Changed to Prevent Reoccurrence?**

\_\_\_\_\_

**Complete on reverse of form or separate sheet if necessary**

**Was any other type of Incident Form Completed?**

**Reference No.**

### 3. Example Template

Registration form for Reporting Complaints Errors and Adverse Events		
	Date Reported : ..... ..... Employee : ..... .....	Quality Manager Number .....
Informant		
Name : Department / Address :.. Postcode / Place : Phone number :		
Nature of complaint or adverse event		
Corrective actions		
Suggestions		
Program Director :		
Incident Closed: Date:		

**4. EXAMPLE TEMPLATE FROM AN ALLOGENEIC INPATIENT DAILY REPORTING PRO-FORMA (PART OF) SHOWING HOW DEVIATIONS MIGHT BE DOCUMENTED**

**ALLOGENEIC TRANSPLANT DAILY PRO-FORMA**  
**TO BE COMPLETED IN FULL BY PHYSICIAN ATTENDING AT ALL TIMES OF REVIEW**

PATIENT DETAILS

TODAY'S Date: \_\_\_\_\_ Days Post-Transplant: \_\_\_\_\_

WEIGHT: \_\_\_\_\_ Kg Performance Status \_\_\_\_\_ [Good -ECOG 0-1; Poor - ECOG 2-3]

COMPLETE ON DAY 0 ONLY

**Source of Stem Cells:** \*Bone Marrow/Peripheral Blood/Cord Blood/Other  
**Ex-Vivo Manipulation:** \*Yes/No.....If "Yes": \*Negative/Positive Selection  
**Cells actually infused:** TNC = \_\_\_\_\_ x 10<sup>8</sup> /Kg CD34 = \_\_\_\_\_ x 10<sup>6</sup> /Kg

*Adverse Events/Reaction to Infusion of Cells:* \*Yes/No

If "Yes", has an IR1 been completed: \*Yes/No

Conditioning Regimen Used

Timetable in Notes YES NO

\*\*\*Was there a Deviation from Planned Timetable YES NO \*\*\*\*

If Yes, please give details

WBC x 10 <sup>9</sup> /L:	ANC x 10 <sup>9</sup> /L :	Hb g/dl :	Platelets x 10 <sup>9</sup> /L :
G-CSF	Yes	No	Date Started:
Platelets Needed Today	Yes	No	

**5. EXAMPLE TEMPLATE**

<b>ADVERSE EVENT AND NEAR MISS REPORTING PROCEDURE HEADINGS STEM CELL TRANSPLANT PROGRAMME STANDARD OPERATING PROCEDURE</b>			
<b>TITLE: ADVERSE INCIDENT AND NEAR MISS REPORTING</b>			
Code	Issue	No:	No. of Pages:
			Copy No:
Replaces:		Revision :	
<p><b>INDICATIONS FOR PRACTICE</b></p> <p><b>AUTHORISED PERSONNEL/TRAINING REQUIRED</b> (Who is responsible for Reporting and what level of training is required)</p> <p><b>PROCEDURE FOLLOWING INCIDENT/NEAR MISS:</b> What Actions <b>MUST</b> be taken and how is safety assured following an Incident or Near Miss?</p>			
<b>WHEN PRINTED</b> This SOP is for single use only. Please destroy following use.			
Effective Date:	Review Date:	Obsolete Date:	
STEM CELL TRANSPLANT PROGRAMME STANDARD OPERATING PROCEDURE			
<b>FURTHER INFORMATION</b>			



## ***Chapter 4: Audit, Validation, Product Tracking, Outcome Analysis & Performance Measurement***

### **Introduction**

Quality Management involves the ongoing assessment of the stability, reproducibility and effectiveness of critical processes in order to continually improve programme efficiency and patient outcome. Quality Management assessment findings are compared to pre-established specification which, when not met, require implementation of corrective or improvement actions with monitoring through follow up assessment to determine the effectiveness of any changes made.

The above statement means that there is a need to ensure that the programme continually runs according to your procedures and that it provides the same results time after time. In order to ensure that this is happening and to provide evidence that centres are constantly reviewing and improving requires investigation and analysis of all of the parts of the transplant patient journey.

Sample templates shown at the end of this Section can be used for completion before audit, validation, outcome analysis etc. are undertaken so that as Quality Manager, you can keep a record and avoid duplication and set an annual timetable of audit.

### **Definitions**

**Audit** – can be defined as a quality improvement tool which seeks to ensure continued improvement through the regular reviewing or checking of systems and processes and the implementation and review of change<sup>4</sup>.

JACIE: “Documented, systematic evaluation to determine whether approved policies or procedures have been properly implemented and are being followed”. Also, JACIE defines Quality audit as “A

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<sup>4</sup> Oakland, J. S. (2001) Total Organizational Excellence

documented, independent inspection and review of a facility's quality management activities to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review".

*JACIE Standard, 5th edition: B/C/D4.8*

**Validation** – is the process of checking whether equipment and processes satisfy certain criteria: for example, checking if a piece of equipment works as it is intended or that a statement in a Policy or Procedure is true (validity). Establishing documented evidence that provides a high degree of assurance that a specific process will consistently achieve a product meeting its pre-determined specifications and quality attributes. A process is validated to evaluate the performance of a system with regards to its effectiveness based on intended use.

JACIE: "Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cellular therapy product meeting its predetermined specifications".

*JACIE Standard: B/C/D4.14*

**Verification** – Verification could be part of the validation process and it is more adequate for equipment.

JACIE: "the confirmation of the accuracy of something or that specified requirements have been fulfilled."

*JACIE Standard: B/C/D4.14*

**Outcome Analysis** – shows the results of procedures & processes and is a means of evaluating practice.


JACIE: "the process by which the results of a therapeutic procedure are formally assessed".


*JACIE Standard: B/C/D4.7*

**Performance Measurement** – performance measurement means using tools such as audit, cause and effect analysis, process mapping in order

to establish how your centre is performing against the Standards or standards you have set.

*JACIE Standard: B3.8.1, B4.1, B/C/D4.2.2.4, CM3.2.1, D3.3.1*

 *The JACIE Standards are a set of measures which centres are working towards meeting and exceeding. One of the JACIE Standards states that Centres should audit some key procedures which are written and undertaken by staff. Are you doing this? How are you performing in terms of meeting this measure? To establish how well you are meeting it, you could set yourself an annual number of procedures to audit e.g. 10. Set this as your Performance Standard. Every year you would then undertake a separate audit to establish whether you have actually audited 10 procedures.*

 *Your centre might set a target yield for cell collection (this is the case in other Centres). In order to assess your performance against the target, you could audit whether you are regularly meeting or exceeding the target and if not, why not.*

## **Audits**

Audits can be **retrospective** i.e. looking back at what has happened or **prospective** i.e. looking at what is happening now<sup>5</sup>. Some of the Audits you are required to do means looking back over a specific time period i.e. 1 year of Engraftment Information. Alternatively you might do an audit of what is happening currently starting on a specific future date.

### **Data extracted from Audit can fall into two categories:**

**Qualitative** – Using perceptions, questioning, obtaining a lot of information which is detailed (patient surveys, staff surveys, and questionnaires).

**Quantitative** – Using numbers and frequency, obtaining figures and trends (activity reports, timing of samples).

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<sup>5</sup> Malby, B. Clinical Audit. (1995). Seutari Press


## The components of Audit are:

**1. Choose what to audit** - There are many different areas you could look at to Audit. The JACIE Standards require that you conduct, review and report audits on regular basis. The results of the audits shall be reviewed, reported and documented at minimum on an annual basis. There are mandatory Audits required by JACIE which are described in the Standards:


- Accuracy of data in Med-A forms
- Donor screening and testing
- Verification of chemotherapy drug and dose against orders and protocol
- Management of cellular products with positive microbial culture results
- External facilities activity
- Engraftment, Morbidity/Mortality
- Policy and Procedures)

Your institution might also have a list of mandatory audits (Hand Washing, Infection Control, Health and Safety) and it might be required to report on these every year.


 *Some Centres have developed Annual Audit Timetables. This was done through firstly identifying an “Audit Lead” within the Department. The Audit Lead does not undertake all of the audits but can support the Quality Manager by helping maintain the timetable and speaking to staff across facilities in order to ensure audits are being done within timescales agreed. The Quality Manager cannot undertake all the audits but can facilitate personnel and provide assistance with collection and analysis of information.*

 *Some Centres have developed an Audit form which is completed by staff wishing to do an audit. The form is useful in that it asks specific questions about who is doing the audit, what the anticipated benefits*


*will be, how long the audit will last and how the audit will be resourced.*

 *An audit can be organized without being previously planned if a non-compliant activity or adverse event happens in order to investigate the causes and propose corrective actions.*

**2. Define Criteria & Set Standards** – for example, when you develop a Policy or SOP, you can put measurable outcomes against them e.g. “target turn-around time for sampling”, “target cell yield from PBSC or BM collection”, “target time to engraftment based upon patient type, transplant type, conditioning regimen used and cell dose infused”. Evidence suggests restricting the number of criteria focusing on two or three as this makes data collection and analysis more manageable. Where possible criteria should be backed up by quoted evidence e.g. policy, literature. If there is little evidence to support the criteria then state this when the report is written up.

 *The Policy and SOP templates shown earlier have a section called “Measurable Outcome”. You might not be able, nor might it be practical to measure every single SOP you have – JACIE provide some mandatory audits which must be performed, your institution might have mandatory audit requirements and you might choose some of the key procedures within your facility. Centres that use the sample templates should state what the target or measurable outcome should be.*

**3. Measure against the Standards – What is happening currently?** – This means performing the audit to see whether you are achieving the targets or measurable outcomes intended from your procedures.

 *Centres approach audit in different ways, there are no set criteria. You can choose to develop your own forms and worksheets in order to extract data from case-notes, you can develop questionnaires and undertake interviews with staff and patients/donors or you can observe the process as it is being done against the documented Policy/SOP or Worksheet.*

#### 4. Compare the Results with your Targets/Measurable Outcomes

This is where you identify whether you are achieving targets or not and, by having done the audit you will have identified what is missing, what was not done correctly, where the potential problems are and what the perceptions of the service are.

A simple example using Quantitative Analysis: *(note different dates)*

Criterion	No. Allogeneic patient sampled <b>1 Apr 06-31 Mar 07</b>	No. who did not receive visit	No. who did	Standard
Patients undergoing allogeneic transplant will be given an invitation for an initial visit to the unit prior to transplant				

Criterion	No. Allogeneic patient sampled <b>1 Apr 07-31 Mar 08</b>	No. who did not receive visit	No. who did	Standard
Patients undergoing allogeneic transplant will be given an invitation for an initial visit to the unit prior to transplant				

It is important to make sure that you comment on the differences in figures and why this has happened.

**5. Formulate Action Plans** – You will develop action plans at different times during your Audit process:

- Before the Audit: to say HOW you are going to do it and WHAT you are going to Audit.
- During the Audit: if you reach a point where you establish that you need to change the way you are doing the audit or the method used e.g. questionnaire by post resulted in a poor response therefore you decided to change the method to questionnaire by interview. You would then need to plan for the change.
- After the Audit: what has the Audit told you? What are the results and how are you going to change anything if anything needs to be changed?

The above components can be shown as a “cycle” for Audit which means that audit is ongoing – once change has been implemented, there is a need to “audit” the change and so on.

- Decide Audit Topic and Set Criteria/Standards
- Compare what happening now with the Criteria/Standards
- Analyse Data and Agree Plans for Change Implementation

### **Sampling**

When undertaking any audit, you will need to establish at what point you are going to start it and which representative sample you are going to look at e.g.:

- 50 CML patients who have Non-Myeloablative Transplants between period 1st January 1995 to 31st January 2007 OR; the NEXT 50 CML patients who are planned for Transplant
- 40 sets of case notes for Autologous patients over period 2005-2007  
OR;  
the NEXT 40
- The next 20 patients who come to the Outpatient Clinic

A “sample” in Audit terms means taking a representative number of items with the same characteristics i.e. Matched Unrelated Transplant Patients, All patients who had BEAM Conditioning or Engraftment in Sibling Allogeneic Transplant Recipients.

The “sample” needs to be large enough to demonstrate meaningful results i.e. picking 5 from a potential 100 transplants of a particular type per annum might show good results but is not representative of the actual total.

### **Audit Preparation**

Preparing for Audit and Analysis of the Data are probably the most time-consuming parts of the Audit Process. Audit in isolation can lead to difficulties e.g. difficulty in obtaining data or difficulty in changing practice because of people not feeling involved.



### **Patient/Carer/Donor Survey - Their Perception of the Transplant Service Offered Within a Centre – Part 1**

*A Centre undertaking Adult Allogeneic and Autologous Transplantation across satellite sites and using off-site collection/processing facilities chose to undertake an audit of patient/carers/donor satisfaction. A subgroup was established to develop the questionnaire and approve the method for undertaking the audit.*

Whether a group is set up or whether individuals undertake the audit following discussions with colleagues, the following must be documented so that it can form part of the final report:

**Reason for the audit** – What led to the decision being made to do this audit?

**Why this topic** – Why was the specific topic chosen?



**Potential Benefits** – What benefit will this audit and potential findings make to the Programme?



*Membership of the group included Medical, Nursing, Collection/Processing and Administrative staff.*

*The **decision** was taken to do this audit because it was important to establish what users of the Service thought about how it had been delivered to them in the past and how they felt now some changes had been made (additional Clinics). The **topic chosen** specifically was **Perception of the Transplant Process from the patient, carer, donor perspective** i.e. seen through the eyes of people receiving it. **Potential benefits** included teams gaining an understanding of how they were perceived, how informed patients felt about what was happening to them, what isolation felt like from the patient perspective, what patients felt about continuity of care as they moved from one area to the other and so on.*

*A Questionnaire was developed to ask for information about what patients/carers and donors felt about the services provided across the entire transplant pathway (referral – collection – infusion – discharge – follow up). **When the questionnaire had been agreed and approved within the Centre, a selection of patients/carers and donors were asked to look at the questionnaire BEFORE it was used, to determine whether they felt there was anything missing and to check that it made sense to them as members of the public who would be answering the questions.** The Centre concerned had to ensure that the questionnaire was **approved by Ethical Committees** before it was used – if you undertake surveys involving patients/carers or donors, you might have to do the same.*

*When the questionnaire was completed, the group then chose a method for retrieval of information. Interview was the best option for this questionnaire as it was several pages long, required examples of supporting information to be shown and the aim of the audit was to obtain **Qualitative Data** (see definition above).*

*The audit was being undertaken to demonstrate consistency in service provision to all patients/carers and donors. **Audit criteria included;** “All Patients will receive an Invitation for an Initial Visit on the Unit prior to admission”, All Patients will be offered the support of Social Workers or others as required, Informed Consent will be obtained from all patients etc. The standard should be 100% across all groups.*

*Within this audit, there was little evidence in literature to support the perception that offers of visits to wards/units prior to transplant improves the overall experience, nor was there much evidence that offering support staff i.e. Physical Therapy or Social Workers did the same. However, informed consent can have consequences if not performed appropriately or at the correct time. Therefore excellent service delivery relies upon consistently offering and doing the same things for all people all of the time. A representative sample was chosen and patients/carers and donors were sent a letter asking whether they would be willing to take part and what the arrangements were for the audit if they agreed.*

*Once agreement had been obtained from patients and carers, dates for interviews were set. The interviews usually took place after clinics where the patient/donor was booked to be seen – the carers came along as support anyway therefore it was not disrupting their routine by undertaking interviews rather than posting out survey forms. The interviews lasted around 40 minutes each.*

### **Analysis of Audit Information**

Not everyone is a qualified statistician and some analyses might require you to find someone with a high level of statistical knowledge. You can analyse data from many audits using simple descriptive statistics supported with tables, graphs and charts.

When compiling the audit report, you must describe the process followed from choosing the topic, through to defining criteria and so on.

You should conclude by saying what the audit achieved and the main learning points gathered, discuss benefits and potential problems and think about whether you plan to repeat the audit.

## Patient/Carer/Donor Audit Example Part 2

*The Patient/Carer/Donor interviews generated a lot of data for analysis. The Centre was able to undertake analysis using simple graphs and charts backed up with statements providing more in-depth information about the particular part of the process being performed*

**Example (note changes/improvement between the two sets of information\*\*)**

<i>Criterion</i>	No. Allogeneic patient sampled <b>1 Apr 06-31 Mar 07</b>	No. who did not receive visit	No. who did	Standard
Patients undergoing allogeneic transplant will be given an invitation for an initial visit to the unit prior to transplant	50	10	80%	100%


<i>Criterion</i>	No. Allogeneic patient sampled <b>1 Apr 07-31 Mar 08</b>	No. who did not receive visit	No. who did	Standard
Patients undergoing allogeneic transplant will be given an invitation for an initial visit to the unit prior to transplant	55	0**	100%**	100%


### **Patient Comments:**


*“It would have been useful to have been able to look around the facilities before coming in as it would have made me feel more relaxed”*


*“It was useful and made me feel better about knowing where I was coming for my treatment”*

### **Other Audit Types & Methods**

 *You might undertake an audit on your own, for example, auditing of some patient case-notes to determine whether the data contained within them meets the JACIE requirements (**Retrospective**).*

 *You could undertake an audit looking at the way your Transplant Clinic is running by observing it for a month (**Prospective**).*

 *You could undertake an audit of the paper trail used for Product Tracking in “real time” as it is actually happening. (**Prospective**) (See **Example in this Chapter**)*

 *Centres are required to Audit Engraftment. In a few Centres, the Collection/Processing facility took the lead on this audit. Data is provided monthly by the Clinical Data Manager to the facility as per requirements. The data was analysed against patient type, transplant type, conditioning, collection achieved, processing undertaken (if applicable), cell dose infused and any adverse effects. The analysis and reporting was done by personnel across the entire Transplant Programme (Clinical/Collection/Processing) and findings were presented at the monthly Audit Meeting. The findings and action plans are then reviewed and developed as part of ongoing monthly Quality Group Meetings (**Retrospective**).*

❓ A Centre identified a problem with the turn around time of Chimerism Samples. A SOP and Policy existed but the problem remained. An Audit of the process was undertaken and it was identified that there was a problem with resourcing the testing at particular times of year. The findings were presented and action plans put in place to improve the resourcing of the laboratory (**Prospective**).

❓ A Centre identified a problem with the length of time taken to obtain cyclosporin results. A SOP and Policy existed but again the problem remained. A meeting was arranged with relevant personnel and the process was worked through using “Process Mapping” which means “drawing” the process on a flipchart from start to finish. It was identified quickly, that the number of steps in the procedure was too many – the samples went to 2 separate reception centres before reaching the laboratory itself. Action plans were developed and the procedure was changed by removing one of the reception centres and providing a more direct route for the samples to go.

*Follow the complete cellular products path: evaluation patient/donor, collection, cryopreservation, infusion, clinical outcomes. Also, consider the interaction and the information exchange between collection facility, processing facility and clinical unit.*

All of the above Audits required the same Audit Cycle to be followed. Preparation did not always require separate groups – some of the audits were done by individuals.

Some of the methods and ways of undertaking audits are described in some of the earlier examples above e.g. questionnaires, interviews, data collection from notes or information systems, observing procedures being performed. Other methods include: looking at ‘Capacity versus Demand’ (are you managing your Transplant Activity? Have you enough Beds for the number of patients you need to Transplant?), shadowing patient groups and so on. **Whatever method is used, you must document why you chose this method and describe how the audit was performed.**

Remember, **Preparation and Planning** is a key part of a good Audit. Consensus on a topic is necessary and recommendation for change need to be agreed amongst the team if the audit is to have a successful outcome.

Explain **when writing up the findings**, who were involved in discussing/planning the audit, how the data were identified, collected, analysed and disseminated and who gave you assistance at any stage in the process.

In order to involve all personnel in the clinical program, it should be useful to report and discuss the findings with all personnel and not only with the director and/or the responsible of some processes/areas. A way to involve all personnel could be to share the minutes of the meeting with the director and/or to send the final report of the audit by email to everyone. Also, a general meeting or small meetings can be organized to discuss the findings and find possible solution (corrective actions) if they are critical situations.

Audit could be performed with short preparation and planning after an adverse event and/or not compliant activities in order to urgently understand why the issue happened and investigate the causes.

A good point to start an audit could be the list of SOP already existent and the coherence between the “real” activity performed by the staff and the SOP

### **Audit Outcomes & Action Plans for Improvement**

When you have completed the audit and done the analysis, you need to compile an **Action Plan** of things areas you are going to look at Improving.

*In the above examples, improvements were made to the PROCESS (sampling, patient journey etc).*

*In order to make the improvements, plans needed to be written which described HOW the improvements are going to be put into place e.g.*

- *Staff had to be fully informed about the proposals and given the opportunity to ask questions or voice concerns – if plans are to work then staff must be happy with them.*
- *Policies and SOPs were developed or changed (if already in place) and everyone had to be made aware of revised procedures.*
- *Training and Education was provided where necessary.*

The process for all of the above formed part of the Action Plan.

### **Auditing the Improvements**

The process of Audit does not end with completion, reporting and Action. When the Actions have been implemented, they should be audited to see whether they are working and deliver what was intended.

### **Validation & Verification**

Validation is a term used to describe the activity required to prove that any procedure, process, equipment, material, activity or system actually leads to the expected results. Verification may be regarded as a part of validation and relates directly to proving that equipment works correctly and actually leads to expected outcomes. Validation/verification activity needs to be undertaken in accordance with documented procedures agreed by the Quality Management Groups and Teams; they must specify all critical steps to be undertaken and the acceptance criteria to be applied. A procedure may include aspects of equipment design, installation, initial operation and performance assessment in the routine environment. A report summarising the results obtained, any exceptions seen and conclusions reached must be completed and reviewed by the quality team as part of the authorisation prior to possible implementation.



*Verification and Qualification of a new Stem Cell Collection Instrument*

***Instrument XXX selected is designed to collect stem cells.***

- *Documentary evidence exists from the supplier confirming the ability of Instrument XXX to specifically collect stem cells in the expected environment and timescales.*

***Installation of Instrument is in compliance with agreed specification.***

- *Machine is sited in selected location, required socket outlets are available, required temperature and humidity of environment is being maintained.*
- *Checks of unpacked instrument confirm no visual damage.*
- *Factory certificate matches serial numbers of instrument, operating manual supplied for XXX Instrument.*
- *Expected version of collection protocol installed, software version matches that on Certificate.*
- *Signed copy of engineer's installation report, covering calibration status and completion of critical settings checks reviewed and retained.*
- *Copy of service agreement retained together with example of engineers service checklist report.*

***Machine Operates as Expected***

- *Supplier training/competency checks for operational staff completed and certificates issued.*
- *Consumables supplied, stored within specified temperature/humidity limits.*
- *Instrument cleaned in accordance with operating manual.*
- *Collection harness loads in accordance with operating manual.*
- *Site Standard Operating Procedures developed and approved covering instrument set-up, actions for alarm events, shut down, maintenance, cleaning.*
- *Report on system with respect to donor comfort and safety and any positive/adverse comments made by donor.*
  
- *The time taken to prepare machine for donation and time taken for collection is provided. Validation log used to enter details.*



- *Calculation of time taken for donation (from needle in to needle out).*
- *Calculation of time taken to prepare machine for donation, from taking harness off machine to being ready for next donor.*
- *Collected product contains CD34 cells at expected levels for the patient/donor.*
- *Further collections undertaken with reduced monitoring with no adverse events reported (numbers dependent upon facility).*

**Validation** signed off for Instrument XXX

### **Ongoing Monitoring**

*(Validation is repeated each time the machine is serviced, when parts are changed in it and if it is moved to another location – Blood Service Quality Manager)*

- *Monitor number of machine breakdowns in validation log*
- *Monitor number of pack related faults found at collection on validation log*

### **Product Tracking**

One of the most important processes in the Transplant Programme is, ensuring the SAFE tracking of the cellular therapy product (PBSC and BONE MARROW) at all stages between donor and infusion into patient. The Quality Manager should understand how the process happens; who is responsible for which part and everything must be documented. Documentation in the medical records MUST include:

### **Identification & Content of the Cellular Therapy Product & Eligibility Status of the Donor**

- There should be a means of allowing outcome information to be fed back to all other facilities involved in the collection processing and distribution of the product.

- The aim of tracking of products is to improve instructions for the shipping and handling of HPC originating from approved apheresis centres or bone marrow collection facilities. Tracking of a product is critical to ensure that the product is:
  - Packaged in transfer packs approved for human cells.
  - Correctly labelled to facilitate donor/recipient tracking. Each labelling phase for all cells should be documented. Material should be labelled for identification and tracing during all phases of procurement, processing, preservation and distribution.
  - Use of unique donor identification number should be incorporated into the cell identification label to facilitate donor-recipient tracking. Labelling should be clear, legible and indelible.
  - Shipped in an outer shipping container (specific for frozen or non-frozen products).
  - Visually inspected to ensure it is in suitable condition.
  - Shipped or handled with a shipping form and specification worksheet corresponding to the written order.
  - Shipping or handling by qualified personnel.
  - Traceability records should be maintained which document the origin and destination of distributed material.
  - The receiver of cells is responsible for verification of shipment and for obtaining and retaining all recipient information. The receiver should provide prompt information to the issuing centre about adverse reactions or technical problems with the use of Allograft or Autograft.

Written procedures should be designed and followed to ensure that product ordering, labelling, packaging, shipping/handling and administration are performed.

The Process of Product Tracking can be audited and validated as a process to make sure that it is working consistently. To do this you would look at the following types of information:



***Product Tracking Process, Documentation & what type of things you could look at to determine that it was being done safely:***

### ***Step 1 – Written Order***

*A Transplant Physician must document in the recipient’s medical record the prospective donors suitability and send a written order. **Check the documentation – is it there or missing – has written order been sent?***

### ***Step 2 – Collection***

*Collection of HPC or BM must be performed according to written procedures in the facilities SOP and Policy manual and the written order. **Has the SOP been followed, has everything written down been done correctly and/or at all?***

### ***Step 3 – Preparation of Product Labelling and Packaging after Collection***

*After HPC or BM collection, the collection facilities complete the patient label with the following details; product identification, name of product, recipient name, date and time collection ends, approximate volume, name and volume of anticoagulant, donor identifier and (if applicable) name, identity and address of collection facility or donor registry, recommended storage temperature. **Are the labels completed correctly and is everything accurate?***

*The collection facility completes the HPC product shipping log as appropriate. **Has this been done and does it include everything described below?***

*The shipping log shall include at least the following details:*

- *Name of product*
- *Recipient Name*

- *Date and time collection ends*
- *Approximate Volume*
- *Name and volume of anti-coagulant*
- *Donor identifier and (if applicable name)*
- *Identity and address of collection facility or donor registry*
- *Recommended storage temperature*
- *Date, time shipped*
- *Courier and tracking number (if applicable)*
- *Name of shipper*
- *Reception section; date and time of receipt, name of receiver, conformity of product container, labelling product.*

*Products that leave the collection facility or are transported on public roads must be shipped in an outer container.*

*The shipping log shall be completed from in-house, national or international shipments.*

*The collection facilities prepare the shipping documentation for international shipment.*

***Check all of the above documentation for accuracy and to find out if it is actually there.***

#### ***Step 4 – Transportation from collection facility to processing facility***

##### ***International Shipment***

*Shipping conditions are approved for pressurised cabin temperature areas of the aircraft.*

*Qualified personnel (nurses/physician) from transplant units collection the product from the collection facilities as appropriate after collection.*

*International Air Guidelines state that a qualified courier shall be responsible for transportation (e.g. from US collection facilities).*

*The collection facilities request and record the shipper's assigned job number or tracking number on shipping log and on the Courier Airbill or other approved shipping documentation. The collection facilities should immediately fax a copy of the completed shipment log to transplant unit and/or processing facility.*

*Transplant unit and/or processing facility is required to track the package with the courier once it has departed from origin.*

***Check this against your SOPs and other documentation you have developed. Observe it as it is happening.***

### ***In-house Shipment***

*Qualified personnel (nurse/physician) from collection facility collect the product as appropriate after collection and deliver to processing facility.*

#### ***Step 5 – Receiving and inspection of product at the processing laboratory***

*The shipping container shall be received by trained laboratory personnel.*

*Outer packaging shall be visually inspected to ensure it is in a suitable condition. Documentation shall be retained including the shipping log. **Check this – watch it being done.***

*The product shipping log and the label affixed on the product shall be compared to verify the information matches both log and label. If the comparison is correct, the shipping form is completed and faxed or copied to collection facility. The original is filed. **Check this as above.***

*The label affixed to the product bag and the request for cell processing log should be compared to verify information correct. Processing can then be performed as appropriate. **Check this as above.***

## **Step 6 – Processing of the product**

*All received products shall be identified with unique numeric or alphanumeric number. **Is this being done correctly in your facility?***

*All process intermediates shall be labelled with new labels as appropriate including stepwise description, unique number or alphanumeric identifier, processing date and time, product identity and donor/recipient information.*

*Non frozen products shall be immediately delivered to the clinical unit following receipt of the written order.*

***Check that this is happening and when written order arrived.***

### ***Frozen Products***

*There should be defined controlled, monitoring and recording of critical parameters for cell storage and discard.*

*Secure storage areas provided for segregation of quarantined cells.*

*Cells shall be packaged and labelled in accordance with information specified by JACIE.*

*Ensure cell acceptability for transportation including documentation of user storage and shipping conditions. If there is any evidence of contamination, tampering, mishandling or failure to maintain required storage, material should not be returned to the inventory.*

*Traceability records should be maintained which document the origin, storage and destination of distributed material.*

***Check that all of this happens in line with your SOPs and other Documentation.***

## **Step 7 – Tracking product to clinical transplant unit**

*The shipping container shall be received at the Clinical Unit by trained personnel.*

*Outer packaging shall be visually inspected to ensure it is suitable. Necessary documentation shall be retained including the shipping log.*

*The product and shipping log and label shall be compared and information verified. If comparison is satisfactory shipping form is completed and faxed or copied to the collection/processing facility. Original form is maintained.*

*The label, request for processing and donor/recipient ID is verified. If satisfactory, administration is performed.*

*The Clinical Facility shall complete the administration log to maintain traceability to allow tracking to original source and donor.*

***Check all of this as above.***



*An Audit and Validation of Product Tracking was undertaken in one centre with the Quality Manager working with the Collection/Processing Quality Manager. You don't have to do this on your own. You could get everyone who is part of the process involved however, they should not audit their own part of the process i.e. if someone is responsible for writing the label then they should not audit how well they are doing it.*



*Examples from centres includes specific forms and written orders used for the entire process of donor/patient workup, arranging for cell collection, storage, arranging cells to be returned to facilities (if applicable), procedures for safe preparation, thawing (if applicable) and infusion of the cells with monitoring forms used to collect information on adverse events which is related back to all areas involved. Engraftment data is also provided to all facilities and regular audit of Engraftment outcome is undertaken. Case note audits will*

*verify that the complete process is being followed. In some centres the Clinical facility uses external collection/processing facilities, specific forms have been developed which include feedback forms for adverse events such as product damage, incorrect labelling, severe reaction during infusion and engraftment data.*

## **Outcome Analysis**

Standards of healthcare quality can usually be based on assessment of structure, process and outcome of care. In general, outcomes are the effects and end results of health care practices and interventions on patients. They are ultimately what you are trying to achieve or avoid if the potential outcome in question is undesirable. Outcome analysis is the process by which the results of a transplant procedure are formally assessed. It includes a series of actions for evaluating the effectiveness of the health care and for identifying the most promising therapies and transplant approaches given the available medical evidence and healthcare resources. Outcome analysis allows the transplant team to understand the effects of their practice and improve quality. Its relevance is due to transplant involving high treatment-related risk, significant practice variations and transplants being expensive to perform.

- You should choose outcomes that will be good Standards of quality. The relationship between the quality of care provided and the outcome is dependent on the processes and the structure of care in place. Change in health status could be attributed to changed quality of health care and can, in turn, affect outcome for example; change in structure of care and processes used to undertake that care.

Outcome analysis can be a complex process but the fundamental requirements are really quite simple:

- You should regularly look at the results of what you are doing
- Analyses that MUST be done are
  - 100 Day Mortality
  - Time to Engraftment



- Recipient Outcome after infusion of a product with a Positive Microbial Culture

**Some processes upon which Clinical Outcome Analysis can be performed include:**

- Time to Engraftment (Mandatory)
- Day 100 Post Transplant morbidity/mortality (Mandatory)
- >1 Year Post Transplant morbidity/mortality (Mandatory)
- Instances of Acute GvHD Grade III or above <Day 100 Post Transplant
- Instances of Chronic GvHD Limited or Extensive > 1 year Post Transplant
- 1 Year Post Transplant Survival all patients

**Some processes upon which Patient Oriented Outcome Analysis can be performed include:**

- Quality of life post Transplant
- Late Effects (fertility etc.)
- Satisfaction with care

**Some processes upon which System & Process orientated Outcome Analysis can be performed include:**

- Quality of Information in case notes and effect on day-to-day care structure
- Annual Training, Education and Competency Assessment
- Induction of new staff and their participation in the Quality programme
- Use of drugs and therapeutics

Unlike audit, outcome analysis does not directly assess the quality of performance, it only allows for inference about the quality of the process and structure of care. Not all patients who experience a poor process of care suffer a poor outcome however, it is important to ensure

that the intended outcome is consistent with the systems and processes put in place by each facility.

Policies and Procedures should describe in detail the steps to be taken in order to do Outcome Analysis. The process for Outcome Analysis should follow the PDCA quality cycle processes of Planning (what you are going to analyse), Doing (undertaking the analysis), Checking (that what you have done was correct) and Acting (taking action to improve based upon the findings).

### **When to Perform Outcome Analysis**

The JACIE standards ask for details of Engraftment and Morbidity/Mortality outcomes at a minimum annually.



*Some centres undertake Quarterly Reporting of Clinical Outcomes by patient type and disease groups. Some undertake Engraftment Analysis Reporting at least twice a year. Outcome Analysis on a specific patient post-transplant forms part of one Centres Clinical Review Meeting which takes place every month whilst Day 100 Mortality is reviewed twice a year.*

### **Defining Patients**

When undertaking analysis of outcomes, it is important that you define the patients or subgroups of patients whom you will be measuring. Outcome analysis requires you to collect a comprehensive number of cases in the same way as was described in “Sampling” under the Audit Section.

### **Collecting Data**

The most common information sources for outcome analysis are the Patient and Donor Medical Notes, Clinical Databases and Care Plans relating to Cellular product collection and infusion.

### **How are you going to measure?**

All intended outcomes should be measurable. Did the treatment/equipment/process you followed provide the outcome result you expected?

Reference results for outcome Standards (the range of numbers/results you are going to use to establish whether your outcome is good or poor) can be taken from international/national guidance, governmental guidelines, evidence-based research, and other information about equipment and techniques used in processes. Some methods may use questionnaires or scales whilst qualitative methods (see Audit Section) can include interviews or direct observation.



### ***Preparing to undertake Day 100 Morbidity/Mortality Analysis***

*The first question is “Why are you performing this Outcome Analysis”? Morbidity/Mortality Analysis can be used to compare your centre outcomes with national and international evidence based studies, it can be used to determine whether your facility is having higher or lower successful or unsuccessful outcomes and you can investigate the possible reasons for these outcomes. It can also be used to look at changes in your own institution over time, for example after adopting a new policy on patient selection. It is an opportunity to provide educational information to different grades of staff from providing background into processes which happen to people which result in a positive or negative outcome.*

1. ***Agree Timeline*** – Centre went for 12 Calendar Months.
2. ***Data Collection Sources*** - Database, Case Notes, Laboratory Results, Collection Facility, Processing Facility.
3. ***Information Collected*** - Transplant by Type, Gender, Median Age at Transplant, Time Period, Diagnosis to Transplant, Previous Treatment provided, Donor Source, Status of Disease at Transplant, Whether full or reduced intensity or type of conditioning for Autologous, Number of Cells Collected PBSC or Bone Marrow,

*Dose Infused, Adverse Events During Infusion, Post Transplant Infections and Complications, aGvHD Score and Site if Applicable, Transplant Mortality D100 and Cause Transplant Mortality >D100 to 1 year and Cause.*

4. **Information Analysis** - *Simple statistical analysis can be performed for some of this information whilst some analyses might require more complex statistical analysis. There are software products and other statistical packages available to help perform such analyses but you need to understand statistics to be able to use them. The Centre performing this Outcome Analysis had the required software and staff with skills required to perform the analysis.*
5. **Present Findings** - *The data was presented at a Clinical Review Meeting using PowerPoint Slides. Attendance at the Review Meeting should be noted by use of the Attendance and Signing-In Sheet (See Chapter 2 Templates). Any discussions about the findings must be minuted and notes of action to be taken and by whom.*
6. **Action Taken** - *When the data is presented, leave time for discussion about next steps and action plans if required. The Action Plan could form part of the monthly Quality Management Group Meetings.*
7. **Action Plan Examples** - *There might be an identified need for further SOPs or Policies. There might be a required change in practice i.e. a drug or dose change which will require changes to documentation, staff training and possibly Trust Approval.*

*There might be a need to undertake some further Infection Control monitoring which will require the input of the relevant departments, briefing of staff, training of staff and possibly result in changed practice.*



## **Failed Engraftment Outcome Analysis**

*Templates at the end of this section provide a list of Outcome Analysis Definitions for Collection, Processing and Clinical Areas.*

Depending upon the type of Centre you are will determine how information is passed between each area:

**Basic** – Information and products contained in single facility and not passed between facilities.

**Advanced** – System in place to show how information/products are passed between facilities

### ***The Components for Engraftment Outcome Analysis;***

1. ***Title:*** *The percentage of patients without ANC  $>0.5 \times 10^9$  /L achieved and sustained for 3 consecutive days without decline for  $>3$  days.*
2. ***Timeline:*** *Annually.*
3. ***Patients:*** *All patients with administration of any type of HPC product with therapeutic intent of any disease or support of other therapy.*
4. ***Information Source:*** *Specific form extracted from medical records and laboratory. Describe personnel and sections of the programme responsible for this form.*
5. ***Measurement:*** *Equipment and analysis used by the haematology laboratory; reporting and recording of the data.*
6. ***Formula:*** *Number of patients with ANC  $\geq 0.5 \times 10^9$ /L achieved and Sustained for 3 consecutive days without subsequent decline for  $\geq 3$  Days. Denominator – total number of patients with any HPC product administration.*

7. **Definitions:** *Engraftment is considered to take place when the ANC in the patient's peripheral blood rises above  $0.5 \times 10^6/L$  before additional treatment to obtain grafting is given. Graft failure includes no engraftment or lost graft (Primary or Secondary graft failure).*
8. **Adjustment:** *Primary disease and stage at transplant. Type of Transplant, Type of Donor, Period of Transplant.*
9. **Assessment Criteria:** *There may be several standards to achieve. Minimum acceptable, optimal or best attainable result.*
10. **Related Processes:** *If measurement results indicate poor outcome, consider what problems in the process might have made them happen. Was the process done correctly, were there adequate staff in place, did everyone have training?*
11. **References Used:** *EBMT, MED-A/B Forms Manual<sup>6</sup>.*
12. **Presentation:** *Report presented and Oral presentation at quarterly review meeting.*
13. **Observations:** *What were the findings that came out of the Analysis and what does research suggest might happen to make the results appear as they have e.g. in allografts, there can be graft loss with normal blood levels due to autologous reconstitution.*

## **Outcome Assessment & Review**

When you measure and review outcomes, you should explain the process used in your final report (same as for Audit above). Outcome review could follow the process as shown in the example below:

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<sup>6</sup> [www.ebmt.org/Contents/Data-Management/Registrystructure/MED-ABdatacollectionforms/Documents/MED-ABFormsManual.pdf](http://www.ebmt.org/Contents/Data-Management/Registrystructure/MED-ABdatacollectionforms/Documents/MED-ABFormsManual.pdf). Accessed 25/03/2013.

- Presentation and Discussion of Results to all relevant staff. Include an assessment of whether the outcome meets the Quality Criteria and what impact there might be in terms of quality of health care structure provided.
- You could undertake a SWOT Analysis of the Transplant Programme – look at the Strengths and Weaknesses in the processes which might have led to positive or negative results.
- When Results are negative, you should find out the causes that explain the results.
- You could work through the process asking what happened at each stage and did we do all the right things? Compare with your Policies and SOP's.

Improvement Plan: whatever the results are, you should propose improvement actions whenever possible. By regular review of the tasks performed every day, you are able to see where improvement might be made. Simple change might be possible as a result of Outcome Measurement

### **Performance Standards (Process Improvement Plan)**


A Process Improvement Plan is designed to show how the results of the Audits, Validation and Outcome Analysis are being used to set down priorities for areas of the Transplant Programme which need to be improved.



*Some centres have added an additional section to the Quality Manual (See Chapter 6) with the heading “Process Improvement Plan” whilst others have opted to develop a separate document containing actions and timescales.*


When the information has been collected (using methods described earlier) and reports and presentations have been done, there is a requirement for discussion and action planning, particularly if results are negative i.e. “patient feels unhappy about lack of information about

what is happening to them” or “Cell Collection Machine breakdown rate is higher than expected” or “Donor Health Clearance from the Registry does not contain enough information for our needs”.

 *Discussion around action plans can take place at the Quality Management Group, a Management Review Group or a separate specific group to deal with the particular problem might be established e.g. “Patient Information Group”. It is important that representation on groups is available from all areas involved.*

The Action Plans you discuss will be noted formally and written up in the form of a Process Improvement Plan. The Process Improvement Plan should contain the following:

- Details of the processes you are trying to improve
- Details of the areas where these processes take place i.e. Clinical Unit, Collection Facility, and Processing Facility.
- Details of the numbers of staff involved in the processes – who is responsible for which part of the process
- Details of any documentation in place to support the current process i.e. Policies and Standard Operating Procedures
- The Actions required to improve the process e.g.:
  - Simple Action Development of Patient Guide and other information as suggested from patient survey.
  - More Complex Re-Validation of Stem Cell Machine, discussion with supplier re ongoing breakdown problems,
  - Testing of machine against several components.
  - Changes to Donor Clearance Forms at Registry – not totally in your control.
- Details of who is responsible for the Actions
- Dates when Actions should be completed
- Details of Expected Outcomes

 *In some centres groups meet monthly but frequency will be determined by the scope of the plan and actions required.*



## **Development of Performance Standards and Process Improvement Plan**

*The Quality Management Group are responsible for development of this plan together with the overall Quality Plan. The group calls in relevant personnel depending upon the scope and area concerned. Sometimes the group may form into sub-groups to work on specific projects i.e. Patient Information.*

**Prospective** – *The group set Performance Standards on an annual basis i.e. identifies the processes with measurable outcomes and sets these down in a checklist i.e. key standard operating procedures, cell yields, JACIE Standards etc.*

**Retrospective** – *Where audit has identified issues and problems, the group will develop a list of priorities for action in order to make improvements.*

*The group might then brainstorm the potential solutions (if not obvious) taking information from more experienced personnel as required to establish what is possible and what is not.*

*The group might split down the projects into sections and assign actions to members. Timescales will be given. All of this is documented in the Plan.*

*The group might meet more frequently to keep each other up-dated.*

*All information about each Process being looked at for possible Improvement will be documented in the plan.*



### **Some Examples of Common Deficiencies Noted**

*The procedures have not been validated and they don't include expected results for any processing step. There is no procedure for equipment validation, no policy for procedure validation.*

*The inspector saw no direct evidence of validation studies of marrow collection procedures being performed although adequate specific SOPs were seen. The inspector did not see labels for marrow collection.*

*The amount of cells collected is always higher than the requested number. However, this does not appear on a validation document.*

### Example Templates Provided For This Section

<b>Number:</b>	<b>Title:</b>
1.	Sample Audit Report Forms
2.	Outcome Analysis
3.	Validation Report Pro-Forma
3.	Outcome Analysis Reporting Templates
4.	Process Improvement Plan Format

## **1a. Example Template Audit Report Form**

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**Title of project:**

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\* Audit reports tend to range in length from a few to a dozen pages, depending on the size of the audit.

- 1. Reason for the audit**
- 2. Criterion or criteria to be measured**
- 3. Standard(s) set**
- 4. Preparation and planning**
- 5. Results of data collection ONE**
- 6. Description of change(s) implemented**
- 7. Results of data collection TWO**
- 8. Conclusion**

**1b. Example Template Audit Report Form**

<b>Name:</b>	<b>Division:</b> <i>what area you work in</i>
<b>Position / Job Title:</b>	<b>Specialty:</b> <i>e.g. BMT</i>
<b>Email:</b>	<b>Tel:</b>

**Title:** *Put the audit title in here*

**Project Team: (who is going to be involved in the audit?)**

<b>Name</b>	<b>Job Title</b>	<b>Specialty (where they work)</b>	<b>Role within Project (data collection, Supervisor etc)</b>

**Participation Details:**

<b>What areas will this audit impact on? (e.g. another profession, my Institution)</b>	<b>Who in this area have you discussed and agreed this audit with? Name:</b>	<b>Job Title</b>	<b>Date Agreed</b>

**Background:** *why is the audit being done*

**Aim:** *What is the audit expected to achieve*  
**Objectives:** *Give examples of WHY this audit is being done*

**1b. Example Template**

*Before starting an audit this is completed and passed to the quality manager or the QM might have done the audit themselves*

Project Lead: *\_who is the Lead\_* \_\_\_\_\_ Job Title: \_\_\_\_\_

Person Undertaking Audit (if different from above): \_\_\_\_\_

Job Title: \_\_\_\_\_ Contact Number: \_\_\_\_\_

Proposed Audit/Survey Title: \_\_\_\_\_

Main Aim of Audit: \_\_\_\_\_

Is the Audit: National \_\_\_\_

Regional \_\_\_\_

Local \_\_\_\_

Does it relate to any Local or National Regulations  
\_\_\_\_\_

What are the Main Objectives e.g. what standards are you auditing against for the audit?  
\_\_\_\_\_

Start date \_\_\_\_ Completion Date \_\_\_\_\_

Still Ongoing , e.g.; Year-on-Year Collection of data?

What does the audit involve, e.g. questionnaire, interviews, case note sampling?

Amount of Time proposed to dedicate to the audit:

Other staff involved, e.g. medical, nursing, admin (please give details of any other departments that should be involved or might be affected):  
\_\_\_\_\_

Perceived benefits or resulting service changes that might arise from the audit?

What other areas will be affected by the audit?

**2. Example template Outcome analysis**

*This is completed and passed to the quality manager Or completed by the QM if they are undertaking the audit*

This is done so that the outcomes and lessons learned can be shared

Project Lead: \_\_\_\_\_ Job Title:

Person Undertaking Audit (if different from above):

Job Title: \_\_\_\_\_ Contact Number: \_\_\_\_\_

Audit/Survey Title: \_\_\_\_\_

**Main Findings:**

**Proposed or Resulting Service Changes**

**Proposals written into Process Improvement Plan Y N**

**Status of the Changes**

Completed

Ongoing

Other

**Lessons for Others:**

Date of Implementation of Service Changes \_\_\_\_\_

Date of Re-Audit (if applicable) \_\_\_\_\_

**3. Example template Stem cell transplant programme validation report**

Project Title  
Project Reference  
Dept Responsible  
Manager Responsible

**PROPOSAL**

**Purpose of Validation**  
*Why is this validation taking place?*

**Validation Team Leader**  
*Who is doing the validation*

**Summary of Change proposed**  
  
Associated SOPs and Equipment that has been Validated  
  
Title of new SOPs required if there is a need

**ON COMPLETION**

**Summary of Validation Results**  
  
  
  
  
(Attach detailed results)

**VALIDATION OUTCOME**

Full Acceptance/Qualified Acceptance/Rejection \* (Attach Non-conformance Report(s) if not full acceptance)

Signed: Team Leader..... Quality Manager.....  
Date introduced into routine use..... \* Delete as required



#### 4. Example Template Actions and Results.

The Actual Plan should contain more information about WHY these areas are being given priority for improvement.

#### PROCESS DEVELOPMENT AND IMPROVEMENT PLAN

The department has a development plan for the next year to improve the service, this is outlined below:

	TITLE	ACTION BY	RESULT	KEY
1.	Implementation of Quality Group which is site specific but continues to link to Centre QMG		ACHIEVED	<i>Colour coding was used to reflect where improvements were generated from the same project i.e. an Audit might generate several improvement opportunities so link them together in your plan</i>
2.	Implementation of revised Donor Selection Strategy			
3.	Implementation of Electronic Document Software			
5.	Implementation of Discharge Packs following Patient Survey			

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## ***Chapter 5: Writing & Reviewing the Quality Manual***

*JACIE Standards: B/C/D 4.1*

### **Introduction**

The Quality Manual (QM) is a written description of how your centre performs the different aspects of Quality as described in the earlier chapters. The QM does not have to be stand-alone, serving only the Transplant Program.

For example, the Clinical Program may choose to participate in an existing quality management programme in its affiliated hospital. In such a case, the written QM should include all elements listed within the JACIE standards and clarify the nature of participation and interactions with other areas and/or institutions.

An integrated Transplant Programme may have one QM that addresses all aspects of Clinical, Collection and Processing. There should be provision for communication of information between key elements of the Transplant Programme including vendors and collaborators.

The Quality Manual is coordinated by the Quality Manager, and written, if possible, by a Quality Group, or ideally by Programme Director.



*Some centres formed a Quality Group(s) and then started developing the QM. Other Facilities already had Manuals in place but had to adapt these to ensure they met JACIE requirements.*

The type of facility you work in will influence the type of Quality Manual you write, specifically with regard to the level of detail you include about the interactions between the different areas.



*A Centre Undertaking Allograft/Autograft but using separate Collection and Processing Facilities would develop a fairly comprehensive Manual which provides details of how the different*

*parts of the quality programme (described in chapters earlier) interact and work together e.g.:*

- A description of the meetings held where all parts of the service discuss things together*
- A description of how information is shared*
- A description of how documentation (policies and procedures) is developed*
- What they are and communicated across all facilities*
- A description of which Audits/Analysis are cross-facility and so on.*



*A sample Quality Manual used in a Centre undertaking Adult/Paediatric Transplantation on two sites with Collection/Processing done by a third party at a different site would develop a Quality Manual that provides details of how the different clinical sites work together and how both interact with the third-party.*

## **How is the structure of the Quality Manual?**

The following are recommended to form part of the Manual:

### **1. Organisational Profile (Facility description)**

This is an overview or description of your facility, where it is located, how many beds/staff, population you serve as a facility, the type of procedures you undertake i.e. Allogeneic only, Collection only, Autologous and Allogeneic, Paediatric and/or Adult etc. The profile gives basic but important information about your services.

The Collection/Processing profile would also be documented under this heading

### **2. Definition of the Quality Management Programme**

In this part you will describe the function of the Quality Management Programme. You can describe the objectives of the programme – what the organisation’s expectations are as a result of having a quality

management programme in place and the indicators you choose to evaluate it.

### **3. Process impact of the Quality Management Programme**

Under this heading you could describe how the programme will influence all parts of the services provided i.e. the pathway for patients including; referral, information, treatment delivery, health and safety, training etc.

### **4. Quality Assurance**

Under this heading you would describe the aims of your facility and describe how you are going to ensure that quality is embedded in everything your facility is doing e.g. patients will be well informed about their diagnosis, treatment, investigations, the transplant with associated risks and benefits and feel confident about their treatment and care. Policies and procedures will be evidenced based, reviewed at a minimum every two years and will be audited for compliance.

### **5. Organisational Structure**

The chart is a diagrammatical picture of your Centre and its facilities; it should clearly show lines of responsibility and authority (See Chapter 1).

### **6. Agreements & Key Relationships**

Describe how Third Party Agreements are developed, who holds the agreement, who signs these agreements and how often they are reviewed, e.g. Third Party agreement with the Collection/Processing Facility or Donor Registry.

### **7. Key Personnel - Roles & Responsibilities**

In here you would document the team roles and responsibilities. You would describe how personnel interact across different parts of the

service i.e. Clinical and Collection, Collection and Processing, Processing and Clinical etc. Don't forget to mention here the consulting Physicians from the different specialties that provide your SCT unit assistance in the care of your patients and how they interact, specialties such as intensive care, pathology, infectious diseases, etc

## **8. Personnel Qualifications, Training & Competency**

Describe how the Policy is designed, who by and frequency. Say who is responsible for the Policy and its delivery. Don't forget to mention the appraisal process here.

## **9. Quality Management Arrangements**

Under this Heading you describe all of the systems you have put in place.

- **Quality Management Groups** – state when they meet, who attends and what the group is going to do e.g. document development/review, service improvement, education/training, risk management etc.
- Describe **other Groups** you set up in the same way as above. For example, do you have specific **Quality Sub-groups** for Paediatrics and Satellite Centres etc.?
- Describe how you **communicate** across all facilities and personnel – what other meetings are held, do you have briefings, how do staff find out what is happening within and across the facilities.
- Describe the process of **document development and control** i.e. how you decide on a document, who develops it, who approves it and how/where is it located for staff to use, how are documents issued, stored and controlled, how often do you review documents what happens if documents become obsolete etc.

Describe the process you have for **Adverse Event Reporting, Errors, Accidents, Biological Product Deviations and Product Tracking** –

see Chapter 3 for examples – describe how you share information between other facilities.

Describe the process you have for **Audit, Validation, Outcome Analysis** – do you have a rolling timetable for this, how do you share information between other facilities within the Programme?

Describe how you implement Corrective Action or Process Improvement. You could describe the action plan you have and how this was developed – see **Chapter 4 for examples**

### **10. Patient Information/Data**

Under this heading you would describe how patient records are held, controlled and secured within your institution and when shared across other facilities e.g. Collection/Processing as required.

### **11. Medical Staffing Arrangements**

Describe who is responsible for Induction/Training and how evidence of this is documented.

### **12. Nursing Arrangements**

Describe who is responsible for Induction/Training and what evidence of this exists e.g. Competency Checklists etc.

### **13. General Patient Care**

Describe what your institution-wide objectives are e.g. does it have a Mission Statement or Objectives – if so, describe them briefly under this heading.

### **14. Health & Safety**

Confirm whether your Institution has Health and Safety Policies and procedures in place and where these are located and who is responsible for them.

## **15. Process Improvement Plan**

You could describe the plan briefly here and then refer to a more detailed explanatory document.

## **16. Appendices to the Quality Management Programme**

You would add here your SOP/Policy Contents Pages

Your Organisational Charts (Organigrammes) if not included within the main body of written Plan.

### **Who writes the Quality Manual?**

The plan is usually written through collaboration between members of all facilities – Clinical, Collection and Processing. If your Collection/Processing facilities already have Quality Manuals then you could look at these and use them to develop the Clinical Plan.



*A Centre example; The Clinical Programme Quality Manager wrote the Quality Manual for Clinical Operations within the Transplant Centre after discussions and implementation of several systems. The manual was reviewed and agreed by key personnel (Directors, Nursing Sisters, Educators, Data Manager etc) – the Collection/Processing Quality Manager worked with the Clinical Quality Manager to develop an Integrated Plan which demonstrated clearly where links occurred in quality aspects such as Incident Reviews, Quality meetings, Document Development and so on.*

### **How often do you review the manual?**

The Manual should be reviewed at least biannually. Aspects of the Quality programme, for example, compliance with incident reporting



arrangements, compliance with document control systems should be reported at least quarterly and information shared across the Quality Groups and with the Programme Director

The Quality Manual itself will change if the systems or organisational arrangements change at any time therefore it is a dynamic document.

### **Who reviews the manual?**

In some centres the Quality Management Group reviews the Manual. The Manual should be reviewed collectively and the information should be shared across all staff within the facilities so that everyone knows what is expected.

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## *Chapter 6: Maintaining the Quality Management Programme*

### **Introduction**

Maintaining a Quality programme can be challenging. When everything is in place, the inspection is over and all deficiencies corrected it is easy to think “that’s it, it’s done!” Putting in place all of the systems described in earlier chapters is just the start. They are the foundations of your Quality Programme. The next challenge is making sure that people continue to work with them, review them regularly and continually improve them, long after the JACIE Inspection.

The Quality Programme can be described as being like a newly built house. When everyone moves in it takes a while to get used to the different rooms and special things that are in it. People want to keep it nice and make sure everything is as it should be. When people have been in it for a while they get used to it and sometimes this means they will change back to old ways of working – not bothering to keep things tidy!

Maintaining Quality Programmes is the same – at various times, when other things are happening and people are busy, they will choose to work around the system because they think this will get things done quicker. They might change a work practice but not bother to amend documentation, they might not bother to fill in an audit form and choose to undertake the audit anyway, they might stop coming to quality meetings as they are too busy etc.

The vital component of the Quality Programme is the people who work within it. There is a need to keep them motivated but there may also be a cultural change needed within them to keep it going now that the “hard work” has been done. The Quality Managers cannot “do quality” on their own and as the Quality Manager you will need to be supported continually by the transplant team if the system is going to be maintained.

Quality Managers need to remain visible - walk around corridors and wards, go and meet people regularly, keep in touch with them and ask them how they think the systems are working.

You have written a Quality Manual and everyone has signed up to it. You will review it at least ever two years and amend it as and when things change. Alongside it you will have developed a Plan for Process Improvement which will show how you are taking action to make improvements happen.

Make sure you keep the meetings going – Quality Group, Policy Group and encourage the attendees to come along. Regularly remind them that this is an ongoing process.

The Quality programme provides the foundation upon which you can build and develop the Transplant Programme. Senior Staff must continue to promote quality and the benefits it brings to the programme so that staff lower down the organisation feel that it is still an important part of everything you do.

In some centres, there is little maintenance required because the system has become a part of everyday working – this is how it should be. The system should not be seen as “more work” but merely “a way of assessing and proving that what we are doing is right and if not, what we are going to do to change it”.

Advise everyone that the hard work is done. You have the documents all written up and they are available for everyone to use. The Centre has all the forms and worksheets in place to do the tasks required, the audits are planned for the year as are the process improvement projects and there is also a robust method of identifying, reporting and closing incidents and adverse events – this is positive – all that needs to happen now is that people need to keep using all of it.

Use the indicators determined and put in place by the quality management group, they are the real driving system of your quality

system. They're useful first to plan objectives in your Direction review. Secondly to check the efficiency of the SOP's and make corrections if necessary. Finally, to ask senior management for new resources (personnel, equipment etc) if the goals are not reached.

Some Centres produce an Annual Report and have a Management Review Meeting to demonstrate what is happening each year in terms of activity and the Quality Programme itself.

Facilities like Collection and Processing are continually assessed by other authorities and thus they continually keep up to date with their quality programme – if you are a Clinical Quality Manager, talk to the respective Quality Managers to ask how they keep people on-track.

Some Centres demonstrate the benefits of Quality regularly e.g. resolving a problem with a particular part of a process (sampling) results in a quickly changed SOP and a briefing of this to all staff. The communication is important.

The ongoing review of things like documents, adverse event reports, audit results and something actually changing as a result of them demonstrates continued maintenance of quality programmes.

Remember that Quality is a continuous process - it does not start and then stop. Centres are expected to demonstrate that they have not only developed and implemented a Quality Programme but that everyone is working within it and, if asked they should be able to say what the systems are and where the documents are.

### **Keeping the Quality Manager Motivated and Trained**

The Quality Manager has to keep his colleagues motivated but he also needs to motivate himself.

There are many opportunities to network with people in the same role as you:

- **EBMT Conference**
- **Telephone and Email other Quality Managers**
- **Training/Educational Events**

The thing to remember is that you are not the only person doing this role. There are many other people all trying to do the same thing and the advice is – **Share Experience**.

## **Summary**

You have reached the end of this Second Edition of the Quality Guide. We hope that you have found it useful.

This Guide is designed to be added to and developed with more detailed information.

If you have any questions or comments on this guide, please write to [jacie@ebmt.org](mailto:jacie@ebmt.org).

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## *Acknowledgements*

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