Chapter 2

Development of Organizational Quality Management System

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FACT-JACIE accreditation is how a HSCT programme can demonstrate that it is performing to a required level of practice in accordance with agreed quality standards in haematopoietic cell therapy (HSCT). An essential component of accreditation is that a centre must demonstrate that it operates an effective quality management system (QMS). Development of a comprehensive quality management system is often the most challenging and time-consuming exercise that the transplant programme encounters when preparing for accreditation (Chap. 14).

The FACT-JACIE Standards define a quality management system as ‘an organization’s comprehensive system of quality assessment, assurance, control, and improvement’. A quality management system is designed to prevent, detect and correct deficiencies that may adversely affect the quality of the cellular therapy product or increase the risk of communicable disease introduction or transmission. It may also be referred to by other terms [1].

A quality management system (QMS) is a mechanism to ensure that procedures are being carried out in line with agreed standards with full participation by all staff members. In a cell transplant programme, this ensures that the clinical, collection and laboratory units are all working together to achieve excellent communication, effective common work practices and increased guarantees for patients. It is a means of rapidly identifying errors or accidents and resolving them so that the possibility of repetition is minimised. It assists in training and clearly identifies the roles and responsibilities of all staff. Once the required level of quality has been achieved, the

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remaining challenge is to maintain this standard of practice. With a working quality management system in place and adequate resources, the fundamental elements necessary to sustain the program are continued staff commitment and vigilance.¹

The QMS in the FACT-JACIE standards establishes a framework for everyday delivery of HSCT (clinical, collection, processing) in the centre. It also includes guidelines for purchasing, human resources and document control related to the cellular therapy product and patient and donor management. In addition, the QMS includes the preparation of the quality management plan (QMP, or quality manual) (see also Chap. 13), writing of the SOPs, describing necessary processes and their interactions, and the preparation of templates for different kinds of documents and records that will be used (see Chap. 3). These are subjected to very careful scrutiny by management reviews (see Chaps. 6, 9, and 12), internal audits (see Chap. 4) and Corrective and Preventive Actions (CAPA) procedures to deal with and correct any non-conformities detected to keep the quality management system effective (see Chap. 11).

1. Development of a comprehensive QMS is often the most challenging and time-consuming exercise for the haematopoietic cell transplant (HSCT) programme as, at least in the first instance, it often requires a cultural shift in working, especially for the clinical HSCT service. Given the challenges, there needs to be a clear justification when implementing the QMS to motivate the team in terms of benefits of quality improvement for the team, their working patterns and facilities, and ultimately for patients. Professional pride and possible advantage relative to other treating centres from a successful accreditation or certification process may also be drivers for change in culture. The adoption of a QMS as part of the accreditation process also firms up collaboration between departments, services, registries and other ‘third parties’, e.g. national or regional blood services, unrelated donor collection centres and registries. Use of the QMS may also help to meet legal and other regulatory requirements of social and private health insurance systems and clinical trials. The QMS is central to achieving JACIE accreditation, which is now used by many external regulators as an indicator of quality for delivery of HSCT to patients.
2. The QMS should be designed to fit the real organisation of the HSCT program and its broader institution. This should reflect **not** *Work as Imagined* (WAI) but *Work as Done* (WAD) [2], i.e. not how a team would *like* to work but how they are *really* working. The HSCT programme will need to discuss and agree internally the organisational structure of the QMS and assign clear roles. This will inform the quality management plan (see Chap. 7) and summarise the relationships between each of the three services – clinical, collection and processing – e.g. how they are managed, where they are based, staffing and leadership, and whether external or third-party services provide services or components.

¹ www.ebmt.org/accreditation-definitions

3. The QMS will need to show the lines of communication and responsibility across and throughout the entire HSCT program and should summarise staffing and describe what is expected of them.
 - All centres' staff should have clearly defined roles and responsibilities and these should be shown on the organisational chart (Table 2.1). This could then be further explained in the QMP, especially the responsibilities, the Job Descriptions or the contact information. If staff are not directly employed by the same institution, honorary contracts may be necessary. An honorary con-

Table 2.1 List of the personnel who work within the transplant programme at the centre who could appear in the organigramme

Position
<i>Note: not all positions listed here will be relevant to all programmes – centres should only reflect their real organisation, roles and structure</i>
HSCT Clinical Programme Director
Clinical Adult Facility Medical Director, as applicable
Clinical Paediatric Facility Medical Director, as applicable
Adult Attending Physicians
Paediatric Attending Physicians
Junior Doctor
Physician in training
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
BMT Pharmacist
Clinical Programme Quality Manager
Clinical Programme Data Manager
Clinical Programme Infection Control Lead
Apheresis Facility Medical Director
National Blood Service Quality Management
Quality Assurance Manager
Assistant Quality Assurance Manager
Processing Facility Medical Director
Laboratory Technician

- tract gives individuals the right to work in more than their own institution and is good evidence of integration across different organisations.
- The FACT-JACIE standards require that the QMS includes an organigramme or organisational chart (see Chap. 7), i.e. visual representation of the structure of all parts of the HSCT programme, and makes clear who is responsible for what aspects of which services (collection/clinical/processing). It should illustrate who reports to whom and who has responsibility for the different aspects of the transplant programme (Figs. 2.1, 2.2 and 2.3). The structure will enable both new/existing staff and external organisations to easily identify the make-up of the programme and lines of authority. Patients could also be provided with information about the team who are looking after them. The HSCT programme will need to show where the collection and processing take place and the individuals involved. Third-party collection and processing services are likely to have their own QMS which is perfectly acceptable if there are service-level agreements (SLAs, Chap. 8) or contracts in place that define how the respective QMS interact.

Below is a list of roles that should be considered for inclusion in the programme organigramme and sample organisational charts showing differently structured programmes.

The Quality Assurance and Performance Improvement System is a coordinated, comprehensive and systematic plan for monitoring and continuously working to improve the services to support the care that patients receive. It will assist staff in

Fig. 2.1 Example 1 of organisation chart template

Fig. 2.2 Example 2 of organisation chart template

Fig. 2.3 Example 3 of organisation chart template

meeting their individualized objectives and shall be managed by the quality manager. Quality managers are responsible for the development, implementation and maintenance of the QMS, while the clinical program directors, in collaboration with the respective collection and processing directors, shall retain overall responsibility for quality.

Depending on how the HSCT programme is organised and its size, there may be a single quality manager or separate quality managers for each service, i.e. clinical, collection and processing.

Although the overall responsibility for the quality of the HSCT programme lies with the services directors, the quality manager has key roles including, but not limited to, the following:

- Understand the entire HSCT process from start to finish.
- Facilitate the development of documentation.
- Facilitate improvements to standardise and enhance the overall service.
- Support the HSCT programme director and facilities directors and educate the team in establishing and sustaining a quality management culture.
- Coordinate the quality programme.
- Report and communicate minutes of quality meetings between the clinical, collection and processing facilities, and the quality management activities at a minimum quarterly. A description of the process for annual performance review and provisions for continuing education (Chap. 17) also need to be included.
- Communicate regularly with HSCT programme staff (e.g. collection, nursing, administrative, laboratory, consultants, junior doctors, data managers).
- Be visible within the centre and motivate people with respect to quality improvement.

The quality manager must understand how the HSCT process works in various settings (allogeneic, autologous, etc.) and the steps patients and donors follow, for example:

- To understand the collection and processing part of the HSCT process, following a patient, donor and/or product through the process of stem cell collection and processing to understand the pathways for the patient/donor and the cellular therapy product.
- To understand the HSCT process from the patient's perspective, asking the patients for their opinion. For instance, did they get all the information they needed? Was the procedure as they expected?
- To understand the HSCT process from the staff perspective, observing 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 alternative way to do it.

The quality manager must also use standardised control documents, meetings with staff from each of the services, audits as well as methods for reporting, investigating and correcting adverse events whether the HSCT service is fully integrated or comprised of three separate facilities.

One of the key aims of the QMS should be to improve communication and understanding of roles and responsibilities across all the different staff groups within the HSCT program. Poor communication between groups of staff is cited as one of the biggest single causes of quality programme failure [3]. Joint Commission sentinel events analysis between 2004 and 2014 consistently showed poor communication as a contributor to failures or inefficiencies of processes [4].

A quality programme will only be successful if there is communication between all the staff involved. Regular group and team meetings should be set up to maintain and increase integration and ensure that different systems work together (Table 2.2). The QMS and QMP are central to improving communication between staff and departments and to ensure that everybody is clear about roles, responsibilities and processes for decision-making. Examples of template agendas and signing in sheets

Table 2.2 Suggested quality groups/teams

Group	Who	What
Quality management group	Quality manager, HSCT programme director(s), medical staff, senior nursing staff, pharmacists, data managers, collection facility staff, processing facility staff, laboratory staff and clinical trials staff	SOP development/review, audit timetable development, incident reporting, training/educational programme development and service improvement
Clinical policy group <i>This group does not have to be separate from the Quality Management Group and could form part of the same meeting</i>	Quality manager, transplant physicians, nursing, pharmacy and support staff	Clinical policies
Multidisciplinary group	Transplant physicians, nursing staff, collection/processing and other support service staff	Morbidity and mortality meetings : presentations of specific cases allow treatment pathways and outcomes to be discussed
Stem cell facility user group meetings –: <i>in centres where a separate or third party collection and processing facility is used</i>	Hosted by the third-party facility to discuss issues around the service provided	The agenda can include document development where documents are linked, i.e. delivery to the centre, incidents with product delivery, biological product deviations
Other management review meetings.	All directors, quality manager, nursing and medical staff National or regional blood services, unrelated donor collection centres and registries	Look at the entire QMS in relation to other institutional organisations and HSCT referral base
Ward meetings, staff meetings, handovers, etc.	Quality manager, ward team, staff, etc.	To bring quality issues to the ward

serve as evidence of meetings, joint decision-making and integration within the HSCT programme.

Below are suggestions of the types of groups that should be contributing to the maintenance of the QMS [5].

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