Chapter 16

Maintaining the Quality Management Program

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General

In this chapter, we will take a closer look with a global view on the design of a quality management system. Many standards originated a long time ago, including the FACT-JACIE standards. The FACT-JACIE standards were created to satisfy an unmet need, viz., to standardize the quality of care for patients and donors in a field of medical intervention that had high mortality and morbidity rates and operated across international boundaries. We have now arrived in a time when quality management has become commonplace and many things have become much more regular. We even have to watch out that the various quality management systems not to overlap leading to unnecessary duplication. But do we? If you compare three well-known standards such as

JCI, ISO15189, and JACIE, you already see in the general topics that there is overlap. Every single QM system has requirements on documents, education, adverse events, changes. And of course the new CAR-T treatments where JACIE is already very advanced but has to deal with regulations coming from pharmaceutical companies that are GxP based (Good Scientific Practices, where “x” stands for any of the following: M, manufacturing; L, laboratory; T, tissue; D, distribution; C, clinical; PV, pharmacovigilance). Altogether, this puts considerable pressure on hospitals and their staff. So we are no longer setting up a QM system from scratch but trying to find a way in existing QM systems where we need to combine all of them in order to protect our departments from duplication of the same rules and regulations from different standards that are often mandatory by law. Maintaining a QMS is about to become an art. It would be good that the organizations would come

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together to discuss the topics and make sure they are complementary so that valuable time can be saved which in the end is beneficial for the patient.

Establishing and maintaining a quality management system is easier said than done. It requires a lot of time, energy, and full commitment of everyone involved, starting with the (top) management. The time involved may be several years, depending on the scope (part B, C, D of the FACT-JACIE standards; see Fig. 16.1) and the clinical activity (autologous and/or allogeneic transplantation in adults and/or pediatric, cellular therapy) of your system and the starting point. The most important pool of knowledge, however, is the education, training, and experience within the team(s). All standards are initially created by colleagues in the field and, at least for FACT-JACIE, also further developed in the 3-year review cycle.

It all starts with the organization wanting to implement a QMS. Firstly, this ambition cannot have any result without the full support of the top management and the (medical) staff and all supporting staff including all other operational managers. Secondly, it sounds obvious, but your starting point is the knowledge and experience of your employees. A quality management system is there to help you organize it. Compare your own point of view with the standards and you will see that mostly you think the same. That shouldn't be that much of a surprise because the standards have been set up and developed by colleagues in the field. Starting from your own professional point of view keeps you alert and will eventually increase the level of the standard. Blindly following the standards will not.

When team members are assigned tasks in the maintenance of the system, it always goes alongside their primary work. One of the statements a department can make in the policy is that everyone is responsible for the QMS and gets smaller or bigger tasks assigned alongside of the quality manager, next to their primary tasks. This could be a responsibility for a specific document, participating in audits or maybe implementing an improvement if it is the field of expertise. There are so

Fig. 16.1 FACT-JACIE standards, their parts, and QMS. (With permission from EBMT)

many examples in organizations, which you will recognize, where there is no time for these extra tasks. One of the reasons for that is that the number of colleagues involved are too limited and QM tasks are many times last on the list. You can prevent this by making the number of colleagues involved bigger so that they only have one internal audit per year or have to update just a few documents instead of 20 per year. A secretary can be involved in checking transplant data because he or she provides a lot of the input during their daily work, for example by creating and maintaining files. The advantage of this approach is that you reduce the pressure on your department, the medical team, and, therefore, also the patient. If you go one step further, you can use your QMS for education. Team up experienced with less-experienced colleagues in every topic and you will see in the long term that many can perform the same tasks. You will create continuity and less dependence on just a few key staff.

The Setup of the Quality Manual

Here you describe your organization, policy, scope, communication, collaborations, the treatments you offer, education, and so on. Furthermore, you address the topics in a general way linked to documents that go further into detail. Fortunately, the times when the quality manual was hefty tome, that included many or sometimes even all SOPs, are almost gone. The organizational chart (both of the department and the HSCT), shows you how the communication is setup between the facilities. Also, the position of the quality manager relative to the program can be identified here. You see everywhere in the standards that the clinical program director (CPD) is ultimately responsible for everything and must have oversight at all times. But how can this be done in practical terms? By making sure the CPD gets this information in the monthly, quarterly, and annual reports, by discussing with them regularly, including minutes of meeting, and by generating an end-of-year report that is approved by the CPD, you can cover this. It is impossible to have the CPD view every single item but it is possible to give a general overview with the ability to dig deeper when necessary. Make this visible in general in your quality manual and refer to the underlying SOP.

Work Area

The locations of parts of your scope define a large part of your logistics. This has an influence regarding your equipment, transport of cells, communication, and so on. It is not uncommon that parts of the HSCT chain are also a part of another department (for example, oncology or the HSCT lab is part of a bigger lab). Experience also tells us that in a small site, communication is likely to be good because the colleagues are used to really short lines and usually know each other very well.

However, you may see this closeness and familiarity reflected in an out-of-date documentation, and in external audits, it may appear that your document management is poor, even though everyone knows exactly what to do. What is missing is the engrained habit of documenting what you do.

Material and Supplies

It is good to see more and more that hospitals have a general way of buying goods and equipment that are validated by the manufacturer and/or during a first (test) use. Does the equipment perform like we want to? Reports and contracts are kept in a general system. Maintenance is often done internally but sometimes also by specialized companies. For these critical items, it is important to clearly describe how you deal with urgent situations regarding backup and response time agreements with the supplier.

Hygiene

In an environment where HSCT is performed, normal cleaning is not enough. Extra hygienic measures require specialized cleaning methods. This can vary between hospitals and includes the patient rooms with air and water filtering. Analyze what information your hospital already has on cleaning methodologies and routines and add what you as a department find necessary with the help of the JACIE standards. By involving the hospital-wide responsible person, you will achieve a good and natural flow in the way you work and learn from each other. The result will be an extra paragraph in the hospital-wide protocol or an additional hematology protocol with a reference. It can be expected that collaboration will build up shared knowledge. Make sure to train your staff on how it is arranged.

Education

You need the right people to do the work. Their education and experience are the basics. Educational sessions (meetings, on the job training, courses, reeducation after longer leave, congresses, participation in the development of documentation) ensure that continuous education is secured. Describe what is addressed in the initial training program, also termed “introduction,” for new employees. A good educational policy where colleagues see that their annual improvement is facilitated is very motivating. Encourage them also to write down and implement their plans and maybe even send it as an abstract to congresses such as EBMT. It is a great way to recognize their work.

Documentation

All the information mentioned is kept in the famous standard operating procedures (SOP). We have lots of them. The key trick is to make sure that SOPs are relevant and don't overlap with other internal SOPs or maybe general ones that are used in other departments or even across the hospital. Another challenge is also who to assign to be an author, reviewer, or authorizer. More on that topic is discussed in Chap. 3 on documentation.

Changes

Changes are a consequence of the analysis of outcome, adverse events, audits, trends, and daily experience. How to implement changes can differ per case. A standard analysis of influence and impact – even a small one – is recommended. A process that records and documents any changes using a *change control approach* is strongly recommended, incorporating where necessary a risk assessment of the proposed change (see Chap. 18 on risk management).

Validation

The FACT-JACIE standards define validation as, “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.” In order to achieve the aims of validation, you need to know how your processes and methods perform in order to improve and be specific in what to improve. Validation is a tool that helps. You can divide this for example in validation of your equipment. For instance, does the apheresis machine perform within the operational parameters provided by the manufacturer? What objective measures can be used to confirm conformation to the anticipated operational parameters? For example, for an apheresis device, the harvested cell dose based on pre-harvest predictors could be a target. This is comparing expectations against real performance. How do you validate your process? That is more difficult because you need to trace the patient from the first visit until discharged from hospital. Nevertheless, if you combine your documents (electronic), patient file, and all related topics, it is possible to achieve the aim. This is teamwork! By tracing the completed patient pathway, every aspect of your process should be covered. As a suggestion, take five differently diagnosed patients per year and trace their routes and you will uncover any gaps that might be there. You could call this a process audit or a prospective risk inventory (“what if?”). The validation of your methods would be, for example, how you handle your protocols or audit cycle.

Information and Communications Technology (ICT)

The ICT process is usually covered by the hospital systems in general, and therefore it is always a challenge to get a good grip on this area. It is not uncommon that more systems are in use even sometimes in the same department. And because the HSCT chain can cover more departments, you can run into this problem. Together with the other departments and the ICT department, you need to find a way for good communication and fine-tuning. For instance, there may be more than one document management system, different processes in adverse events, different colleagues responsible, and so on. Solutions for deficiencies on this topic mostly start with the upper management in deciding how the process is changed. Due to the many responsibilities and complicated multiple systems managed by the ICT department, you really need to make a solid case on why implementing changes are necessary. Finally, a contingency plan in case of a general ICT system shutdown is an absolute must-have.

Meetings

Meetings and evaluations shows your daily, weekly, monthly, and annual lines of communication. Make sure you describe the individual meetings well and who or per specialty, is attending. There is a never-ending discussion if you need attendance lists or not; however, a list does help a JACIE inspector quickly to determine whether important meetings such as transplant operational planning meetings, QM meetings, and morbidity and mortality meetings are attended by sufficient representation of the department. In particular, to demonstrate that the CPD has oversight, a list provides this evidence. Anything that helps during the JACIE inspection will improve the efficiency of the inspection. Where electronic patient files are in place, you can also be able to see when a treatment/patient was discussed and by whom [not a good way to have oversight]. The best thing to do is describe this in your meeting overview or the protocol related. You need to fine-tune it to your own situation and improve by your experiences.

Outcome

Analysis of treatment outcomes are done on different levels – on a daily basis and over the long term. It varies from discussing a single patient to aggregate outcome results. Together with any benchmarking schemes in your country and or via the EBMT registry, you will get a good insight into how well the program is performing.

Outcome analysis, a summary of important outcomes and review, will teach the transplant team a great deal by spotting trends and helping to indicate where to

make changes. A strong advice would be to categorize generally which sounds obvious but make sure you categorize the same as your adverse events, complaints, audit findings, and so on. If you do this for your whole department, you will be even more capable of making global as well as detailed analysis. For further details, see the chapter on outcome in this book.

Risk Assessments

Risk assessment is a crucial tool that must be a core component of any transplant and cell therapy program. Risk assessment is essential in managing change as part of change control and when introducing a new process, procedure, or therapeutic intervention into the program. The challenge is to keep the risk assessment process simple. You easily drown in too many risk assessments. Define what is important and how you want to do it. A risk assessment is also the result of a discussion about a change in treatment from which the why and how you will put in the (electronic) patient file, without saying it is a risk assessment, so partly what you do on a daily basis.

A Practical Example

In JCI, you are required to use the RSVP (reason, story, vital signs, plan) method for verbal and written communication. While implementing this in a facility, the team realized that they already did this through the electronic patient file, not realizing it was a method. The facility saw this as common sense to do so.

Again, it is important to restate that you always need to check what is already in place before implementing a “new” change. What the exact best way is you will learn during implementing and evaluating and can differ per facility.

Audits

There are many audits described in the JACIE standards (see Fig. 16.2) and they will need fine-tuning depending on the scope of your activities. Do not hesitate to combine audits when possible. They are a great tool for learning and should form part of the educational program for staff. One approach for well-funded departments is to set up a team of auditors with members of every discipline. Make teams with a focus to learn from each other. An alternative strategy is to have a small group of individuals with audit training who help less senior staff members such as trainee doctors and nurses who are given individual audit topics to prepare and present to the department. Audit experience is a mandatory requirement in many countries for trainee medical staff and provides good opportunities to gain experience not only in the audit cycle but also in presentation of the completed audit. Good audits can be

Fig. 16.2 Critical processes that must be audited. (With permission from EBMT)

submitted as abstracts to meetings such as the annual EBMT meeting. The impact that this can have on awareness of processes, who is doing what and implementing changes, is underestimated. Here are some examples of audits that must be performed regularly.

Some take aways:

- Your professional knowledge is your starting point.
- The FACT-JACIE standards are a really good helpful tool when used with the FACT-JACIE manual.
- Involve as many of the staff within the transplant program as possible in small and larger tasks, make it “their” system.
- Make teams for audits and documentation review with the aim to learn and grow.
- Appoint colleagues with a special field of their attention and give them regular opportunities during the year to present and discuss issues.
- Check what is already there, which can be used as a starting point for implementation of new things.
- Ask for input from colleagues in other hospitals who are more experienced on topics that you are not familiar with.
- Have every new colleague meet the quality manager in their initial training program so that new colleagues are familiarized with QM from the very beginning.

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