Chapter 3

Document Development, Implementation, Review, Archive, and Disposal

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General

Documents have many uses in the quality management program. They provide the structure needed for quality assurance through policies and procedures, ensure quality control through forms such as pre-printed orders and worksheets, and support quality management activities through audit reports, outcome analyses, and training records. The quality program needs to identify documents critical to the transplant program. The transplant program needs to describe how the critical documents are conceived, generated, implemented, distributed, reviewed, and stored. All parts of the transplant program require written instructions as to how to undertake key processes. Equally, personnel in the facility should use these documents to carry out tasks and they need to be sure that the document they are using is the current version. Documents (policies, Standard Operating Procedures (SOPs), worksheets, and forms) are the foundation of the quality program as they explain how tasks are undertaken and facilitate the effective operation of the transplant service. An overarching policy encompassing the writing, reviewing, implementation, and control of documentation (the “SOP about SOPs”) is a key requirement.

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Start

Setting up a document management system (DMS) starts with making an inventory of what you have and of what you need. What do you think is required and what are the JACIE requirements? The standards provide a structure whether you are starting from square one or whether you already have a set of transplant-related policies. Transplant centers frequently have pre-existing laboratory and, less commonly, clinical policies, though, very often, the system is so fragmented that many staff are unaware of their existence. From the outset, it is imperative to form a project team as the task is huge and needs constant monitoring and steering.

Some key points to consider:

- Use your in-house expertise
If you make your expertise the starting point, you will make the DMS your own. In the development of documents, review the draft contents against the JACIE requirements. This will lead to useful discussions which will increase the value of your SOPs.
- Use information available in your own hospital
- Other departments in your hospital will already have information and policies that you can use as a starting point. Refer to them in your own documents and this will prevent unnecessary duplication and make yours easier to read, e.g., hygiene and safety policies.
- Don't go reinventing the wheel in developing new policies about which you know little. Ask other hospitals or EBMT quality forum colleagues whether they have information or policies that they might be willing to share. Then, modify them to suit your own requirements.
- Refer to other documents rather than continually lengthening your own new policies and procedures. This will prevent you from falling into the trap of having to constantly revise huge, unreadably large documents. Refer to checklists, papers, and key supportive information.
- Make sure that in-document URL hypertext links always relate to the source document and that they work. You can use the same link throughout your DMS.
- Use job titles rather than the names of individuals in your DMS to avoid the need for document revisions when people change jobs.

Use the quality manual as your starting point. This is a high-level document, so avoid excessive detail and try to keep it short. Refer to SOPs and other relevant documents. In your SOPs, refer to checklists and additional information elsewhere (*see Fig. 3.1*). This makes them more readable and accessible.

Example set-up of the quality manual

1. Organizational profile (facility description)
2. Definition of the QM program
3. Impact of the quality management program
4. Aims of quality assurance
5. Organizational structure and responsibilities

Fig. 3.1 Example document structure

6. Agreements & key relationships
7. Key personnel – roles & responsibilities
8. Personnel qualifications, training, and competency
9. Communication
10. Documentation
11. Adverse events
12. Audits
13. Outcome

Workflow

The quality manager has overview of all documents and is usually assisted by document managers who are clinicians or scientists with a part-time role in quality (see Fig. 3.2). This is a constructive approach in that such individuals have areas of expertise which relate to the documents assigned to them. They are therefore best positioned to ensure that the relevant policies are fit-for-purpose.

The quality manager is the direct link to transplant program management and is responsible for the implementation of the QMS. The quality manager provides a quarterly report to the clinical program director and the management team to keep them up-to-date regarding new documents and revised versions of existing documents. These quarterly reports are included in the annual report and the annual management review, completing the policy Plan-Do-Check-Act (PDCA) cycle for this topic.

Fig. 3.2 Create and review documents

– Author

The first author of a document leads in its preparation and writing and should have relevant expertise. The goal is to produce an advanced draft ready for wider review. This provides an educational opportunity which will be addressed further later in this chapter.

– Reviewer(s)

These are one or more individuals who check the document for factual accuracy and clinical relevance. If required, suggested improvements can be incorporated into a revised version. This person is often from another department and provides different expertise. Such a fresh perspective is often very useful. An example would be a pharmacist reviewing medical policies from the point of view of pharmacovigilance. This is a common approach and helpfully ensures that pharmacists are aware of all new treatments.

– Authorization

The clinical program director (CPD) is ultimately responsible for the transplant program and the CPD (or his/her designee) therefore authorizes all documents. However, the CPD does not necessarily need to review and authorize each document. That would take an additional work week. The non-medical documents can be delegated to members of the management team or the relevant senior, qualified individuals. In such cases, this should be carefully documented in the DMS SOP. If necessary, the CPD can review document metadata in order to monitor its development. These changes can be summarized in the quarterly and annual reports.

Note: Electronic document management systems generally allow for each step in the process to be tracked. This is not the case with paper-based or hybrid systems and care is needed in such cases to ensure that the workflow is robust and easy to operate.

Responsibilities

Involve as many staff as possible when developing new documents. This is crucial. It is common at inspections to find that the DMS has deteriorated – missed review

dates, obsolete policies – as too few people have too many documents to take care of. Tasks end up being repeatedly deferred. This can be dangerous for both patients and clinical staff as treatment protocols must be kept current and have the latest information. It is the job of the quality manager to ensure that newly authorized documents are immediately made available for routine use.

Here are some examples of the appropriate staff to be involved in developing particular policies:

- Treatment and medical and supportive care: (senior) nurse, physician-in-training, nurse practitioner, physician assistant, oncologist, hematologist, pharmacist, counselor
- Policy: management team, team leaders
- Data: secretary, data manager, nurse

Medical systems differ and you will need to adopt an approach that best suits your local circumstances. However, the key take-home message is to involve as many people as possible in order to keep the system going in the long term.

Duplication of Requirements Between Different Quality Systems

Anyone involved in quality is aware of the overlapping requirements between quality systems such as JCI, JACIE, and ISO. The transplant unit may be a component of a wider oncology program; a pharmacy-based QMS might be subject to a different regulator; the pediatric unit may be administratively distinct from the adult unit; and there are often a number of different information and communication (ICT) services networks – whether national, regional, or hospital-based – all available on local workstations. Equally, the hematology laboratory may be accredited to ISO 15189:2012 (medical laboratories – requirements for quality and competence). In general, there are few significant differences between these standards. A useful approach is to follow the stricter guideline and to try to avoid following separate regulations in a given area as it may lead to confusion. For example, if JCI requires three-yearly review and JACIE two-yearly, follow the JACIE requirement.

Unfortunately, the different international standards have evolved and diverged over time, and it is important to bear in mind when creating DMS policies that they meet all of the different regulatory requirements. Inspectors and the EBMT can be made aware of these issues.

Each transplant unit has unique circumstances, based on local logistics and resources. So it is not possible to be prescriptive. Rather, the key principles to remember are that documents need to be kept up-to-date and accessible for everyone involved. Important underlying concepts include the use of technical solutions, cross-referencing between documents to prevent redundancy, and close collaboration with other hospital departments, especially ICT, when setting up and also on an ongoing basis to maintain the DMS.

ICT Systems and Paper Documents

Recent ICT advances have included hospital-wide electronic patient records (EHRs) and remotely accessible document management systems. Some of these allow for treatment protocols to be automatically included in patient records, guaranteeing the use of the current version. More usually, however, each transplant unit is a patchwork of promising innovations and local logistical limitations. The challenge might be physical due to lack of space or financial due to inadequate investment. Some departments manage to set up their own bespoke IT systems. Although an attractive short-term solution, this can pose problems. The hospital ICT department will not provide support when something goes wrong and such a system can leave the unit dangerously reliant on one motivated individual.

A paper-based DMS offers a reasonable alternative but has some challenges of which you need to be aware. These include the revising of policies, filing and archiving, and how to keep everyone informed of new versions of documents. This is the system where you see frequent handwritten notes. If following Good Documentation Practice guidelines, every written update to a document must be signed and dated. This is not likely to happen in a hectic hematology department.

Here again, there is no one-size-fits-all solution. However, using a collaborative common sense approach, it should be possible to put in place a workable system that meets the standards. The basic question you always have to ask yourself is, “How do I get the latest version of the document to the people that use it?”

Education and Document Management

A document management system is a perfect tool for education. Here are some examples:

- New employee: make sure that new employees receive training in the DMS. Consider assigning them documents in their field of expertise. Over time, they can be assigned first authorship.
- As mentioned previously, involve pharmacists in the development of treatment protocols.
- Discuss policy changes at quality meetings. Other means of disseminating information include newsletters, reading lists, etc. If the change is significant, it could be brought to the multi-disciplinary team meeting to ensure that all staff members are informed.
- Secretaries and data analysts use data in patient files on a daily basis. Involve them in reviewing documents in their field of expertise.
- Bring different staff together for collaborative discussions. Taking people out of their silos can lead to productive cross-fertilization of ideas: “I never knew you could do it that way!”

These are just a few examples of how you can use document management systems for educational purposes. Reflect on how this can be done to benefit your program.

JACIE on Document Management

The document control policy shall address the points listed in Fig. 3.3

The JACIE document management standards are straightforward. Documents should have a standard format and should be revised every two years with clear revision dates and tracked changes. They must be authorized by the CPD or designee, contain accurate references, and information on “who modified what, at what time, and why” should be clearly recorded. Methods to ensure safe validation of both electronic and printed versions are also required. Finally, and importantly, maintain a readily available list of all critical documents.

Documents may require revision for several reasons:

- If a staff member makes a clear case for revision
- As a corrective action following an (internal) audit or adverse event
- Changes in regulations (law)
- Changes in standards
- Changes in organization

The DMS SOP should clearly describe these processes. Documents should be easily accessible. Finally, maintain open communication with all staff in the

Fig. 3.3 JACIE and document management

transplant program and make sure management is aware of all significant developments.

Note: Refer to the JACIE/ EBMT manual for the standards and guidance in their implementation.

Source for figures

1. Figures 1 and 2 were created by the author, and Figure 3 is from the EBMT Standards quality management presentation.

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