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Quick Guide to Audit; How to create, plan, perform and report audits

Performing audits is an important activity in a Quality Management system to be able to monitor, improve and develop activities and initiatives. As the role of the Quality Manager's Committee (QMC) is to support Centres in achieving and maintaining their accreditation as well as provide support to the JACIE Office and the EBMT Board in Accreditation issues, the QMC is looking at ways to provide resources for Centres, including this Quick Guide to Audit.

Audits represent one of the principal activities of the quality management program. Audits are conducted to establish whether the program is operating effectively and to identify trends and recurring problems in all aspects of facility operations. Of course, an audit finding can also demonstrate strengths of the Programme/Facility.

Setting up an audit team

An audit team typically consists of three to five employees, including the team leader, who preferably should have extensive experience in the area being audited.

The members of the audit team must be impartial, and hence an auditor must not be solely responsible for the area being audited.

The team will plan and conduct audit within the agreed timeframe, prepare the audit report and, finally, ensure the audit report is accepted by the Clinical Program Director

The audit process

Audit is a process where a group of people analyses the result of data collection from various data sources. Based on the analysis, the group proposes improvement measures.

Audit process has four core elements.

1. Selection and definition of audit area and purpose

It is important that the area to be audited is relevant from the quality management perspective or from a professional, organizational and/or patient perspective. (There are specific audits listed in the FACT-JACIE Standards, but many other areas are relevant to audit in order to measure the quality processes within the department).

It is the audit team leader in cooperation with the QM, who prepares and convene the first meeting of the audit team. Typically, the audit team's first meeting will be a planning meeting, which primarily aims to clarify the scope of the current audit.

It is important that the audit team has a defined remit for the audit before deciding on what data sources to be used. Data sources could include patient records, extracts from databases and observations of working practices or interviewing patients or staff members.

2. Determination of the basis for assessment and data collection

To establish the basis of the assessment means, it is necessary to know the standards for the quality management in the department. This makes it possible to compare the outcome of the audit with desired quality level.

It is important that the data collection method is described precisely in the audit report. This will make it possible to compare data when re-audit is carried out. All employees within the team /department may be involved in data collection.

3. Conclusion and root cause analysis

The audit team will assess the data collected against the required standard (policies, procedures, 'best practise' or international and national treatment outcomes). Based on analysis of the data, the audit team must conclude whether there are any issues and/or areas with potential for improvement, as well as proposed quality improvement priorities or initiatives.

The audit team leader or QM is responsible for ensuring that the Clinic Program Director approves the audit report before the result is shared.

4. Actions and evaluation of interventions

The relevant quality management group discuss the results of the audit, and subsequently decides if any quality improvement initiatives should be established. It may be appropriate to compare with previous audit results.

The results of the audit should be presented to the relevant quality management group to decide on any follow up actions required. These may include quality improvement initiatives, re-audit etc. A corrective action plan should be developed which is deliverable and where roles and responsibilities, as well as expected outcomes are defined. Examples of audit reports and corrective actions plans can be found in: [The JACIE Guide | EBMT](#).

It is prudent to evaluate the success of the corrective actions taken once implemented. This might require a re-audit of the process to ensure that the corrective actions have had the desired effect.

References

FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration. 2021. Available from: <https://www.ebmt.org/8th-edition-fact-jacie-standards>

Mahmoud Aljurf, John A. Snowden, Patrick Hayden, Kim H. Orchard, Eoin McGrath. Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy. 2021. Available from: <https://www.ebmt.org/sites/default/files/2021-03/The-JACIE-Guide.pdf>