



Audit Guide



B Universitat de Barcelona



Executive
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Audit Guide

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I. INTRODUCTION

This Audit Guide aims to evaluate Organ Donation Process in European hospitals and has been developed as a result of the Organ Donation European Quality System (ODEQUS Project), co-financed by the Executive Agency for Health and Consumers, contract PHP 20091108, promoted by University of Barcelona, Spain. It has lasted three years, from October 2010 to December 2013. Fourteen different national organisations and hospitals from eleven European countries have participated in this project.

The main objective of ODEQUS project is to determine the quality criteria of best practices in organ donation and develop Quality Indicators (QI) for Donation after Brain Death (DBD), Donation after Cardiac Death (DCD) and Living Donation (LD) and creating a Pan-European methodology to evaluate the organ procurement performance at hospital level.

This Auditing Guide has been created in order to put together, in a practical and useful way, the criteria and indicators considered essential for the organ donation activities carried out in a hospital level. The ODEQUS experts have collaborated in the development of this Guide, providing their know-how and giving guidance on how to perform audits and what to search for.

This Audit Guide has a standard-based methodology, in which data is collected and performance observed in order to measure current practice and compare it against those criteria. Subsequently, any changes considered necessary are implemented. This process involves reviewing the main processes carried out in the hospital.

This Guide is intended for three different groups of individuals:

1. Transplant coordinators: As a tool on how to monitor the organ donation process within their hospitals and find improvement points.
2. Regional and national transplant agencies: To follow up and control the organ donation process in their hospitals.
3. Auditors: To guide them through an audit, since it contains the main criteria and quality indicators related to organ donation process.

2. METHODOLOGY

An audit is a documented review of procedures, records, personnel functions, equipment, materials and facilities in order to evaluate adherence to quality criteria and governmental laws and regulations. During an audit, performance is reviewed to ensure the items which should be done in terms of quality management are being done and documented, and if this is not the case, it provides a framework to allow improvements to be made.

The QI implementation feasibility will be certified by two types of evaluation:

- Internal audit: performed by a team from the own hospital
- External audit: performed by an external team(national or international).

The internal team collects all the information that will serve first to perform the audit themselves, which afterwards will be analysed by the external team.

Three main aspects have to be considered in the audit: The Information to be collected, the auditor team, and the quality criteria and indicators to be followed.

2.1 Information to be collected

1. Written protocols and procedures related to organ donation and end of life care which are in force in the hospital
2. If the hospital has a Living Donation (LD) program:
 - a. Medical records of all patients who have been assessed as potential living donors in the evaluated period
 - b. Total number of patients who have been enrolled “de novo” in the kidney transplant waiting list during the evaluated period
3. If the hospital has a DCD program:
 - a. Medical records of all patients who have been assessed as possible DCD donors by the Donation Team in the evaluated period

4. It is also important to obtain information from the Donation Team, and if there is any registry that contains information about donors outside the medical records.

3. INTERNAL AUDIT

It is conducted by a team led by the hospital's internal evaluator previously trained according to the recommendations of ODEQUS Training Manual⁽¹⁾. Since the task of gathering all documents (protocols, procedures, medical records, records of the donation team) for both audits usually corresponds to the internal evaluator/auditor, it is highly recommended that the internal evaluation/audit precedes the external one.

3.1 Information to be collected DBD

In case of possible DBD donors, the information to be collected requires more detailed description:

In order to decide which records will be part of the evaluation, several steps must be taken:

1. The internal evaluator has to identify all patients who have died in the Emergency Department or in any ICU or in the Stroke Unit in the evaluated period. The definition of ICU for the purpose of the evaluation is “*any area of the hospital with specialized staff in the management of life threatening conditions, where patients may be mechanically ventilated and where the nurse / patient ratio is at least 1/3*”⁽²⁾. Neonatal units are excluded, but paediatric intensive care units are included.

For each patient the followings should be specified:

- a) A classified identification of the patient (a number or any other code which univocally identifies the patient – hereby called **patient code**)
- b) Age

- c) Hospital unit where the patient died
 - d) Classified diagnosis (a code which univocally identifies the patient)
 - e) Procedures (as ICD 9 or 10). For ICD we need the main diagnosis and three more, as well as three procedures.
2. This information should enable the auditors to identify those patients who died with severe neurological damage and that could be the subject of study as potential donors.

In order to evaluate the workload of the evaluation the auditors must know in advance the number of medical records of deceased patients to review. If the workload is excessive, a random subset of the medical records may be selected.

3. Once it is done, the list of selected patients is sent back to the internal evaluator as the DBD possible cases.

3.2 Audit Procedure

The internal audit team should consist of two professionals; one of them will be the Transplant Coordinator of the hospital audited and the other could be one professional from the Quality Department of the hospital in order to assess compliance to standards and procedures.

The team should decide on the date of the audit and inform the hospital archive department in order to have the clinical records available.

The auditors are expected to review first the documentation previously prepared in the office and enter data required for the Quality Indicators into the computer system.

The audit focuses on ODEQUS quality criteria and indicators provided together with this guide. This methodology is effective in focusing the content of the audit on the defined core requirements regarding organ donation.

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3.3 Audit Report

A report based on the analysis of the “Expected Results” of each quality indicator will be provided. This report will be useful to identify the points to be improved in the Organ Donation Process.

3.4 Remarks

It is essential to include the correct PATIENT CODE assigned to each patient when introducing information in the database, as the external audit team should use EXACTLY the same code.

In addition, all sources of information used by the internal audit team (Clinical records, protocols, procedures, etc) should be available later for the external audit team.

The internal audit could be also performed prospectively. In this case, each clinical record is introduced in the system when it happens (daily) and the evaluations by the audit team are done every 6 months.

4. EXTERNAL AUDIT

The external audit consists of two auditors, one from the own hospital and another from a recognised (national or international) organisation in organ donation.

The SAME INFORMATION used by the internal evaluation team is considered by the external group of auditors.

4.1 General considerations for external auditors

1. The hospital to be audited should be informed in advance about the auditing agenda, the auditor(s) details, the auditing procedure and the audit estimated duration, according to the number of clinical records to be reviewed.
2. The person in charge of the audits organization has to make sure that all necessary documents for the evaluation (the same used in the internal evaluation) is available to external auditors at the date of the visit.
3. The audit objectives and scope should be explained in writing to the hospital direction.
4. The person in charge of the audits organization should make sure that the hospital provides an office and a computer with internet connection for the dates of the visit.
5. Depending on the country legislation, a confidentiality agreement may be signed to guarantee the confidentiality of the clinical records analyzed.
6. The external evaluation team should be in close contact to prepare the audit some days before travelling to the institution to be audited and should also communicate with the person in charge of the audits organization in the hospital.

4.2 Audit Procedure

Two weeks before the visit, the internal auditor has to notify the hospital authorities about the day of the external auditor visit.

The audit is performed by qualified and experienced professionals in organ donation activities, which have adequate technical training and expertise as auditors and knowledge of all steps of the living and/or deceased organ donation process. It is essential that an independent and objective attitude is maintained by the auditors and the audit planning and performance is carried out professionally. The auditors are chosen in such a way to guarantee that the team has the required knowledge and experience to properly examine the hospital. If any conflict of interest is perceived, applicants are entitled to request a change in the auditor's team prior to the audit.

The hospital visit

External auditors are received by the internal evaluator on arrival at hospital.

A meeting should be planned during the visit, including the hospital authorities, the managers of the units involved (i.e., intensive care units, emergency room, donor transplant programs) and director of quality department. The aim of this meeting is to briefly describe the audit, explain its purpose and acknowledge the cooperation of all.

After the meeting, the external team starts reviewing the documentation previously prepared in the office and enter data, required for the Quality Indicators, into the computer system.

The audit focuses on ODEQUS' criteria and indicators provided together with this guide. This methodology is effective in focusing the content of the audit on the defined core requirements regarding organ donation.

The time necessary for the external audit is decided in advance by all professionals involved. Depending on the size of the hospital and the number of clinical records to be reviewed, two or two and half days might be appropriate.

All auditors should be experienced and trained in auditing. In some cases, depending on the country, it might be necessary to have an interpreter with the team to verify documentation and facilitate the entire process.

4.3 Audit Report

Following the audit team delivers a preliminary Report before leaving the Hospital. The main points of this report will be communicated to the hospital director in a final meeting.

Later on, a final report based on the analysis of the "Expected Results" of each quality indicator will be sent to the Hospital Director and Transplant Coordinator.

After the external audit, a comparison between both internal and external reports might be made in order to find new points of improvement in the organ donation process of the evaluated hospital.

4.4 Remarks

The role of the external team is NOT to assess the quality of medical care provided by the hospital.

The internal evaluator can offer help to explain how information is organized in the medical records. But he cannot help with a particular patient or discuss it with the external evaluators.

The PATIENT CODES must be exactly the same ones used by the internal evaluators.

REFERENCES

1. M Manyalich, X Guasch, M Gomez, G Paez, L Teixeira and ODEQUS Consortium. ODEQUS Training Manual. Universitat de Barcelona, 2013.
2. Beatriz Domínguez-Gil, Francis L. Delmonico, Faissal A. M. Shaheen, Rafael Matesanz, Kevin O'Connor, Marina Minina, Elmi Muller, Kimberly Young, Marti Manyalich et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transplant International* 24 (2011) 373–378
3. Coll, E; Czerwinski, J; De la Rosa, G; Domínguez-Gil, B (coord.) Guide of recommendations for Quality Assurance Programmes in the Deceased Donation Process
DOPKI Project, 2009. Available on:
<http://www.ont.es/publicaciones/Documents/DOPKI%20GUIA.pdf> (January 7, 2013)
4. M Manyalich; C Fernández; A Navarro; T de By; O Cornu; A Nanni Costa; et al.
European Quality System for Tissue Banking_ EQSTB.
Available on:
http://www.aebt.org/congreso2008/Documentacion/Programa_Cientifico/Sesion_II/Ponencias/mmanyalich-po.pdf
5. European Directorate for the Quality of Medicines & HealthCare (EDQM). European Committee of Experts on Organ Transplantation (CD-P-TO). Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells. 2010, 4th Edition.
6. Rubin, H R; Pronovost; P; Diette, G B. From a process of care to a measure: the development and testing of a quality indicator. *International Journal for Quality in Health Care* 2001; Volume 13, Number 6:99. 489-496.
7. Lombarts, M J M H; Rupp; I; Vallejo, P et al. Application of quality improvement strategies in 389 European hospitals: results of the MARQuIS project. *Qual Saf Health Care* 2009; 18 (Suppl 1): i28-i37.

8. Martín, M C; Cabré, Ll; Ruiz, J et al. Quality Indicators in critically ill patients. SEMICYUC. Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronárias. Update 2011 Available on http://www.semicyuc.org/sites/default/files/actualizacion_indicadores_calidad_2011.pdf (January 7, 2013)