

# Guide to the Quality and Safety of Organs for Transplantation



**EDQM**  
6th Edition  
2016

## Why a European Guide?

Transplant medicine and transplantation have progressed during the last decades in a way that nobody would have imagined before. The transplantation of organs offers major therapeutic benefits and improvements to quality of life and is, in many cases, the only life-saving treatment for end-stage organ failure. The most critical factor remains the supply of organs for transplantation, but only organs recovered following strict quality and safety standards are likely to function satisfactorily, and careful evaluation of donors is essential to minimise the risk of transmission of infections or malignancies. Furthermore, since human organs can currently only be derived from the body of a person, strong ethical principles need to be associated with their use.

The Council of Europe is the leading standard-setting institution in this field. It actively promotes the non-commercialisation of organ donation, the fight against organ trafficking, and the development of ethical, quality and safety standards in the field of substances of human origin.

The European Committee on Organ Transplantation (CD-P-TO) is the Steering Committee in charge of transplantation activities for the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe). One priority of its work programme is the elaboration of the *Guide to the quality and safety of organs for transplantation*. As a result of the work of many leading European experts in the field, this Guide constitutes a common standard for all Council of Europe member states and beyond, based on the long-standing expertise and knowledge of the EDQM and the involved experts.

## Who is the Guide designed for?

This 6th Edition of the *Guide to the quality and safety of organs for transplantation* collates updated information to provide an easy-to-use source of reference and guidance to: all professionals identifying possible organ donors; co-ordinators managing the process of donation after death and that of living donation; professionals responsible for the allocation and clinical use of human organs; quality managers and health authorities responsible for overseeing donation and transplantation programmes.

## What information does the Guide contain?

This Guide includes practical guidance dealing with quality and safety aspects of donation and transplantation. It aims at maximising the quality of donated organs and minimising risks, thereby, improving the rate of successful and safe organ transplantation. It covers: important ethical principles that must always be respected in any donation and transplantation procedure; recommendations for the identification and referral of possible deceased organ donors and the determination of death by neurologic criteria; recent views on donor management; guidance on the assessment of donors to prevent the transmission of infectious, malignant or other diseases; state-of-the-art information for organ procurement, preservation and transportation; guidance on donation after circulatory death and living donation; and the most up-to-date information to ensure the quality and safety of organs during the multiple relevant procedures that take place from donation to transplantation.

The Guide includes instructions on 'minimum standards' based on the relevant European Union (EU) Directives in the field. It thus provides technical support to EU Member States in their implementation and assistance for those states outside the EU that are considering adopting the EU requirements in their legislation. However, this Guide goes beyond these standards by providing additional advice, based on best practices consistent with current scientific knowledge, expert opinion and the results of many EU-funded projects. It also refers to recent developments that may be reflected in future updates of the EU legislation, where necessary and relevant, thereby providing advance information and recommendations regarding developments in the field.

## What has changed in this 6th Edition?

In the sixth edition, all chapters carried over from the fifth edition have been thoroughly updated and extensively revised. In addition, some new and important chapters have been added.

The new chapter on 'Determination of death by neurologic criteria' addresses the fundamental principles of brain death diagnosis and expands on the key decisions that follow.

The new chapter 'Consent/authorisation for *post mortem* organ donation' focuses on the different legal systems for consent or authorisation to enable the donation of organs and tissues after death and provides guidance on how to approach and communicate with families.

The former chapter on assessment of donors has been divided into two new, more comprehensive chapters. The first on 'Deceased donor and organ characterisation' describes how to assess the suitability of donors and organs, on undertake an adequate risk-benefit analysis and to optimise organ allocation. The second on 'Donor and organ assessment and selection criteria' clarifies the difference between expanded criteria and non-standard risk donors: a quality versus a safety concept. From the safety perspective, this chapter provides a classification of donors in terms of risk of disease transmission.

The chapter on 'Risk of transmission of infectious diseases' has been revised to include up-to-date developments in the field of emerging pathogens. Additionally, screening algorithms have been extensively updated and a new section on infections of the central nervous system has been included.

The chapter on 'Risk of transmission of neoplastic diseases' has been fully updated and revised providing guidance for the assessment and grading of the risk of transmission for an extensive list of malignancies present in the donor history or incidentally identified at the time of organ recovery.

The new chapter on 'Living Donation' provides an overview of an activity that is progressively expanding in Europe, addressing a number of legal, ethical, medical, technical and organisational aspects of this practice.

The new chapter on 'Donation after circulatory death' focuses on donation from persons declared dead using circulatory criteria. It gives concrete recommendations for the development and optimisation of programmes for both controlled and uncontrolled donation after circulatory death, providing useful guidance to authorities and professionals initiating or consolidating this practice.

The chapter on 'Biovigilance' has been expanded, particularly describing how to identify, report, assess and manage severe adverse reactions and events. In strict alignment with the EU directives, the chapter clarifies concepts and provides guidance on the implementation of good vigilance and surveillance practices.

Finally, the chapter on 'Quality management in organ donation and transplantation' has been completely rewritten to provide detailed principles of quality management systems in organ donation and for transplantation activities, including separate reviews of government and health authority responsibilities.

## Publication and purchase of the Guide

The Guide is available in book and online versions, in English. The electronic version of this Guide can be downloaded for free and the book version purchased at the EDQM Store. For more information, please visit the EDQM website: <https://go.edqm.eu/OTg> or scan the QR code.

The EDQM also publishes and regularly updates the *Guide to the quality and safety of tissues and cells for human application*, which provides information and guidance for all professionals involved in donation, banking, transplantation and other clinical applications of tissues and cells of human origin, and the *Guide to the preparation, use and quality assurance of blood components*, which provides principles and standards designed to ensure the safety, efficacy and quality of blood components. Additionally, the EDQM annually publishes the *Newsletter Transplant*, which collates international figures on organ donation and transplantation throughout Europe and beyond.



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