Guide to the quality and safety of ORGANS FOR TRANSPLANTATION

www.edqm.eu

@EDQMCouncilofEurope

@edqm_news

EDQM
8th Edition
2022

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

GUIDE TO THE QUALITY AND SAFETY OF ORGANS FOR TRANSPLANTATION

PURPOSE AND BACKGROUND

Organ transplantation has progressed significantly in recent decades, yet demand for transplantable organs still far exceeds supply – with important consequences for health, since organ transplantation is often the only available treatment for end-stage organ failure. As with all substances of human origin, transplantation of human organs entails a risk of disease transmission. Comprehensive quality systems and appropriate donor screening and selection must therefore be in place to guarantee the best possible transplantation outcomes. The *Guide to the quality and safety of organs for transplantation* contributes to meeting these needs.

The Council of Europe is the leading standard-setting institution in this field. Its work on transplantation is co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM). The European Committee on Organ Transplantation (CD-P-TO) is in charge of transplantation activities, promoting the non-commercial donation of organs, tissues and cells and the fight against organ trafficking, and developing ethical, quality and safety standards in the field of organs, tissues and cells.

TARGET AUDIENCE

The Organ Guide informs professionals on the most recent advances in the field and provides technical guidance to ensure the safety and quality of human organs intended for transplantation, with the ultimate goal of improving successful and safe organ transplantation rates. Easy access to this information is essential for all stakeholders concerned – professionals involved in identifying possible organ donors, co-ordinators managing living or deceased donation pathways, those responsible for the allocation and clinical use of human organs, quality managers within the process, and health authorities responsible for donation and transplantation programmes.

NEW IN THE 8th EDITION

All chapters have been thoroughly revised according to the state of the art, and new and important chapters have been added. A set of clinical questions was formulated for **Chapters 5** and **11** – using the PICOS approach (population, intervention, comparator, outcomes, study design) – to formulate evidence-based recommendations where appropriate. A research agenda section has also been included at the end of most chapters, identifying priority research areas, where evidence is insufficient or non-existent.

Chapter 2, *Identification and referral of possible deceased organ donors*, addresses challenging practices such as elective non-therapeutic ventilation and admission to intensive care units, incorporating donation into end-of-life care.

Chapter 3, *Determination of death by neurologic criteria*, provides a detailed description of the physical and ancillary tests necessary for the diagnosis of death by neurologic criteria.

Chapter 4, *Consent/authorisation for post mortem organ donation*, describes current European legal frameworks in this area and best practice in supporting relatives of deceased organ donors and communicating bad news.

Chapter 5, *Management of the potential donor after brain death*, now includes more details on nutritional support.

Chapter 6, *General donor characterisation, assessment and selection criteria*, presents a donation process flowchart, with cross-references to relevant chapters of the guide.

Chapter 7, *Specific organ characterisation, assessment and selection criteria*, provides information necessary to evaluate each organ individually.

Chapter 8, *Risk of transmission of infectious diseases*, includes up-to-date recommendations in the field of emerging pathogens, with screening algorithms.

Chapter 9, *Risk of transmission of cancer*, covers risk assessment where a donor may have a history of malignancies, addressing malignancies caused by donor oncogenic viruses and donors with genetic predispositions to cancer.

Chapter 10, *Risks related to the use of organs from donors with other conditions and diseases*, provides recommendations on organs from donors either with conditions such as inherited or autoimmune diseases or who are themselves organ transplant recipients.

Chapter 11, *Organ procurement, preservation and transportation*, has been entirely rewritten, providing up-to-date information on organ procurement and *in situ* and *ex situ* preservation techniques.

Chapter 12, *Donation after circulatory death*, presents best practice in realising both controlled and uncontrolled DCD pathways.

Chapter 13, *Living donation*, now considers aspects of pancreas, small bowel and uterus living donation, in addition to the psychosocial aspects of living donation.

Chapter 14, *Paediatric donation*, covers all aspects of deceased donation in children, and addresses outcomes involving paediatric donors.

Chapter 15, *Donation of vascularised composite allografts*, has been revised to include uterus transplantation in detail.

Chapter 16, *Biovigilance and surveillance*, has been considerably revised to provide guidance on how to identify, report, assess and manage severe adverse reactions and events.

Chapter 17, *Achieving and measuring quality in organ donation and transplantation*, includes detailed principles of quality management for organ donation, procurement and transplantation.

Chapter 18, *Measuring outcomes in transplantation*, reviews the factors to be considered when assessing transplantation outcomes.

Chapter 19, *Communication of risk and shared decision making*, addresses consent for living donation and transplantation and provides guidance for crisis management.

HOW TO OBTAIN A COPY

The *Guide to the quality and safety of organs for transplantation* is available in English, in print and electronic form. The electronic version can be downloaded for free and the print version purchased from the EDQM Store. For more details, visit the EDQM website: **https://go.edqm.eu/OTg** or scan the QR code overleaf. Information on non-official language versions produced by Council of Europe member states is available on the EDQM website: **https://go.edqm.eu/translationtsto**.

ADDITIONAL GUIDANCE

Guide to the quality and safety of tissues and cells for human application – technical guidance on the donation and human application of tissues and cells of human origin: **https://go.edqm.eu/TCLeaflet**.

Guide to the preparation, use and quality assurance of blood components – European harmonised standards on safety, efficacy and quality requirements for blood components: **https://go.edqm.eu/BloodGuideLeaflet**.

For further information on additional guidance documents in the transplantation field for governments, professionals and the general public, please visit **https://go.edqm.eu/TransplantReports**.

PREMS 123922 – CED-22-07