Guide to the quality and safety of ORGANS FOR TRANSPLANTATION
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WHY A EUROPEAN GUIDE?
In recent decades organ transplantation has progressed in a way that no one would have imagined earlier. Still, demand for transplantable organs far outweighs supply – with important consequences for health, since organ transplantation is the best, and often the only available, treatment for end-stage organ failure. Kidney transplantation is also cost-effective compared with other renal replacement therapies, even in low-resource environments. However, as with all substances of human origin, transplantation of human organs entails risks of disease transmission that must be controlled by appropriate donor screening and selection.

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 these activities, which promote the non-commercial donation of organs, tissue and cells, the fight against organ trafficking, and the development of ethical, quality and safety standards in the field of organs, tissues and cells.

WHO IS IT AIMED AT?
WHAT INFORMATION DOES IT CONTAIN?
The Organ Guide updates 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. It is essential that all concerned – professionals involved in identifying possible organ donors, co-ordinators managing the process of donation after death and that of living donation, 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 – have easy access to this information. The Organ Guide supports professionals on a practical level to improve the rate of successful and safe organ transplantation.

WHAT HAS CHANGED IN THIS 7TH EDITION?
All chapters have been thoroughly revised according to the state of the art, and new and important chapters have been added. Chapter 2, Identification and referral of possible deceased organ donors, has been updated, and now includes a section devoted to the application of intensive care to include the option of organ donation into the end-of-life care plans of patients. Chapter 3, Determination of death by neurologic criteria, provides a detailed description of the physical examinations and ancillary tests needed in the diagnosis of brain death, and gives guidance on professional practice following the determination of death by neurologic criteria.

Chapter 4, Consent/authorisation for post mortem organ donation, describes the current European legal frameworks covering consent for donation, and expands the section on best practice in supporting relatives of deceased organ donors and in communicating bad news, both in the process of donation after brain death and in that of donation after circulatory death. Chapter 5, Management of the potential donor after brain death, has been updated, based on current knowledge in the field. Additionally, new sections have been included on nutritional support, management of brain dead multi-organ donors, optimisation of the timing in performing organ recovery and donor management during organ procurement.

Other enhancements to the Guide include the complete revision of Chapter 6, General donor characterisation, assessment and selection criteria. It now summarises all issues related to the donor without focusing on specific organs, covering the risk of disease transmission and measures to be taken to avoid such unintended transmissions. Chapter 7, Specific organ characterisation, assessment and selection criteria, provides the information necessary to evaluate each organ individually.

Chapter 8, Risk of transmission of infectious diseases, has been revised to include up-to-date developments in the field of emerging pathogens, together with screening algorithms for an extensive list of pathogens. It also considers the impact of new direct-acting antiviral agents in the treatment of hepatitis C virus infection, proposing updated recommendations on the use of organs from donors infected with this virus. Chapter 9, Risk of transmission of neoplastic diseases, has been entirely rewritten to provide current criteria used in risk-assessment when transplanting organs from donors with existing or past malignancies. Grading of risk is provided for an extensive list of malignancies that may be identified in the donor history or be discovered at the time of organ procurement. Chapter 10, Risk related to the use of organs from donors with other conditions and diseases, has also been revised to provide recommendations on the use of organs from donors with conditions other than poisoning and inherited diseases, e.g., allergies and auto-immune, neuro-degenerative and demyelinating diseases.

Chapter 11, Organ procurement, preservation and transportation, provides updated information on organ procurement, on different perfusion solutions, and on new trials in preservation (e.g. machine perfusion, cold-storage, normo/hypothermic storage). Chapter 12, Donation after circulatory death, now includes a detailed description of the use of in situ preservation techniques that may help improve the quality of organs recovered from donors after circulatory death. It also includes, for the first time, recommendations on heart transplantation from this type of donor. Chapter 13, Living donation, now also addresses aspects of lung living donation, ABO- and HLA-incompatible living transplantation and kidney paired exchange programmes.

The new Chapter 14, Donation of vascularised composite allografts, addresses this novel field of transplantation, which in many countries is still being explored under research protocols. Chapter 15, Biovigilance and surveillance, has been expanded to provide guidance on how to identify, report, assess and manage severe adverse reactions and events. Chapter 16, Achieving and measuring quality in organ donation and transplantation, has been updated to provide detailed principles of quality management for organ donation and procurement, as well as for transplantation activities. Finally, the new Chapter 17, Measuring outcomes in transplantation, reviews the factors to be considered when measuring outcomes in transplantation.

HOW CAN I OBTAIN A COPY?
The official version of the Organ Guide is available in book and online versions, in English.1 The electronic version of the Organ 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/OTq or scan the QR code.

ADDITIONAL GUIDANCE DOCUMENTS
Technical guidance on the donation and human application of tissues and cells of human origin has now been moved to the dedicated Guide to the quality and safety of tissues and cells for human application. For blood and blood products, please refer to the Council of Europe Guide to the preparation, use and quality assurance of blood components. For further information on additional guidance documents for governments, professionals and the general public in the field please visit https://go.edqm.eu/TransplantReports.

1 Non-official language versions are produced by some member states. Please check our website for more information on available languages: https://go.edqm.eu/translationsto.