



Data Disclosure Policy

Eurotransplant International Foundation



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1. Introduction

The basic principles on data confidentiality and security of personal health information of patients within Eurotransplant are laid down in the Eurotransplant Data Policy document.

The Data Disclosure Policy sets out the broad principles and practice relating to the release of data by Eurotransplant. It describes:

- the principles underlying this policy;
- procedures for the release of data.

2. Purpose

The purpose of this policy is to ensure that the use and disclosure of personal identifiable health information complies with applicable privacy laws. It sets out the broad principles and practice within Eurotransplant relating to the disclosure of data.

The purposes for which the data are collected by Eurotransplant are:

- allow / support allocation, being the core task of Eurotransplant;
- make the allocation process to authorized users and national authorities traceable and transparent;
- further improve the allocation process / rules;
- support scientific research.

3. Scope

This policy applies to:

1. the disclosure of data for planning and management purposes;
2. the disclosure of data for research purposes to Eurotransplant centres or to third parties;
3. the disclosure of data to external requests for purposes other than research;

All access to personal health information must comply with applicable privacy laws and Eurotransplant's privacy policies and regulations.

4. Legal framework

Eurotransplant collects and processes personal identifiable information in order to provide allocation services to patients on its waiting list.

Eurotransplant also collects identifiable follow-up transplant information for quality reasons and allocation development purposes.

Eurotransplant is committed to complying with data protection legislation (Dutch Data Protection Act (DPA)) and the Eurotransplant Data Policy which describes the responsibilities and provides principles and guidelines covering all aspects of processing personal information.

Information on the deceased is not protected by the DPA, although the duty of confidentiality may require that sensitive medical information must be protected.

Anonymous data, in which the information which might identify an individual has been removed, is not considered personal data and is also not covered by the DPA.

The disclosure of personal identifiable data is considered to be a way of processing data. Under the DPA this means that the rules on fair and lawful processing of data must be met. No personal identifiable information may be disclosed to any third party unless it is lawful to do so.

According to the DPA the disclosure of personal health data is justified if:

- The data subject has unambiguously given his/her consent to the disclosure;
- The disclosure is required for the performance of a contract to which the data subject is party (e.g. the medical treatment agreement);
- If there is a statutory or legal obligation to disclose the data;
- The disclosure is necessary to protect the vital interest of the data subject;
- The disclosure is in the legitimate interests of Eurotransplant or of a third party to whom the data are to be disclosed and does not prejudice the rights, freedoms or legitimate interests of the data subject.

The DPA also allows personal data to be disclosed to third parties without the consent of the data subject for the purpose of scientific research or statistics provided:

- The research serves a public interest;
- The processing is necessary for the research or statistics concerned;
- It appears impossible or would involve a disproportionate effort to ask for consent and
- The processing for research purposes does not adversely affect the individual privacy of the data subject to a disproportional extent.

In all other cases the consent of the data subject is mandatory.

Eurotransplant shall not transfer personal identifiable information to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of individuals in relation to the processing of personal data. Anonymised research data can be transferred outside the European Economic Area.

5. Data Classification

Eurotransplant applies the following classification of data:

- Identifiable record level data: data which includes elements that directly identify an individual (e.g. name subject);
- De-identified record level data: data which are considered to carry a high risk of identification whether or not combined with other data (e.g. ET number);
- Aggregated data: data which is put in a format which prevents the revealing of the individual's identity;

6. Data collection

Eurotransplant is collecting personal identifiable information on:

- patients listed on the waiting list;
- donors reported to Eurotransplant;
- all relevant steps of the allocation process (offering/acceptance/procurement);
- transplantations;
- follow-up of transplants.

Eurotransplant holds no more personal information about an individual than to the extent that is needed for the purpose of the information gathering.

7. Data Access

Eurotransplant distinguished the following groups of users with access in ECS to personal health information:

- Internal users (employees of ET);
- Eurotransplant authorized users: authorized members of the Eurotransplant community or otherwise linked to Eurotransplant;

8. Data Disclosure

8.1. Health care providers

Transplant centres of the Eurotransplant member states have access only to the data of their own patients. Authorized users have access to (de-)identifiable record level data in ECS to perform their assigned duties with respect to the transplantation procedure.

Eurotransplant can only provide identifiable patient data for research purposes from other centers if explicit consent is given for this by the patients concerned.

A transplant centre shall send its request for data for research purposes to the Eurotransplant Advisory Committee involved, with copy to the Medical Director of Eurotransplant.

Eurotransplant only releases centre specific data with the approval of all the centres included in the data release.

8.2. Scientific investigators

Eurotransplant supports scientific research which promotes the development of allocation and transplantation of organs.

Eurotransplant discloses anonymous data for health research.

Eurotransplant discloses de-/identifiable data from patients for research purposes only if the patients concerned have given explicit consent.

De-/identifiable data can only be released without consent of the patients concerned in case the specific legal requirements of the DPA as described in chapter 4 are met.

The investigator shall send his/her request for data for research purposes to the Eurotransplant Advisory Committee involved, with copy to the Medical Director of Eurotransplant.

The research subject shall not be identifiable in published research results or in publicly available datasets, unless with consent of the research subject, or in case the information is already in the public domain.

The procedure for requesting data for scientific research is incorporated in ANNEX 2.

8.3. National Competent Authorities

Eurotransplant provides on request of National Competent Authorities of its member states aggregate reports on allocation and transplantation outcomes. Eurotransplant shall release this data in a standardised format.

National/competent authorities and its representatives can be granted access to personal identifiable information of their national transplant centres when exercising statutory or governmental functions (e.g. audits).

8.4. Legal/Police requests

Legal requests for personal identifiable information must be submitted in writing to the general director of Eurotransplant. When information has been approved for release, a copy of the relevant data will be provided.

Eurotransplant will only release original records if a Court order is received requiring this.

Release of data requires the approval of the general director of Eurotransplant.

8.5. Registries

Eurotransplant maintains a follow-up registry of transplanted patients for allocation development. Eurotransplant obtains data for the registry from various sources: allocation services, exchange co operations with other registries and through scientific research projects.

Data originating from research studies are collected and processed by Eurotransplant with consent of the research subject.

Data exchanged with other registries require the consent of the patient and the respective centre.

An agreement for data exchange with a registry is required. This agreement should be reviewed every 5 years.

8.6. Media/Public

Eurotransplant publishes information on organ allocation and transplantation outcomes and results of scientific research regarding allocation development on its website. Eurotransplant makes statistical information publicly available in an aggregate way.

In responding to requests from the media or the general public, Eurotransplant shall only release aggregate data. All data released to the media/public can be distinguished as aggregate data, customized aggregate data. For the use of data/footage made available by Eurotransplant with acknowledgement of copyright Eurotransplant may include conditions for use and/or reproduction of the data.

Data requests by the media/public shall be addressed to the communication department of Eurotransplant.

Release of customized aggregate data requires the approval of the medical director of Eurotransplant.

9. DEFINITIONS

Authorized users	healthcare organizations and professionals which are directly involved in the process of organ donation and transplantation on behalf of a transplant centre and who have been granted access to the ECS by Eurotransplant;
Collect	this means to gather, acquire, receive or obtain the information by any means from any source;
Consent	any freely given specific, informed and explicit indication of his or her wishes by which the individual, signifies agreement to personal data relating to him or her being processed;
Data subject	the person the data pertains to;
Donor	a person who donates one or several organs, whether donation occurs during lifetime or after death;
ECS	the computerized information system that is managed by Eurotransplant in which information concerning donors, recipients and transplantation follow-up is entered in a uniform way in accordance with the ENIS Manual;
Personal data	any information relating to an identified or identifiable natural person;
Processing	any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, erasure or destruction;
Recipient	a person who receives a transplant of an organ;
Transplant centre	a healthcare establishment, a team or a unit of a hospital or any body which undertakes the transplantation of organs and are authorized to do so by the Competent Authority under the national regulatory framework of the member state concerned;

ANNEX 1: Procedure for data disclosure / presentations

Eurotransplant is committed to encourage innovative scientific research and develop follow-up data recourses to improve organ allocation and transplant outcome.

This document outlines the procedure for accessing information contained in the Eurotransplant Computer System (ECS).

- Authorized Eurotransplant-users (including members of Eurotransplant Board and Advisory Committees): have access to or can request data available in ECS regarding:
 - 1) Their own centre on a patient level:
 - a. patients on the waiting list;
 - b. donors offered to patients in their centre during the allocation process, donors used for transplantation in their own centre permanently (aggregated);
 - c. information on the allocation process for their recipients (peri-allocation report);
 - d. follow-up data including outcome data for their own centre (Kaplan-Meier analysis).
 - 2) Other Eurotransplant centres on a centre level with cumulative descriptive statistics on:
 - a. registrations on the waiting list;
 - b. waiting list dynamics;
 - c. transplant activities.
 - 3) Follow-up data including outcome data on a national level, with the approval of the respective Eurotransplant Advisory Committee. A written request, including study proposal shall be sent to Eurotransplant and will be evaluated by the respective Advisory Committee.
 - 4) The representatives of an individual transplant program have access to the complete current overview of the national waiting list concerning the organs that are transplanted at the respective transplant centre. In this list all patients from other transplant centres are anonymized.
- Public users have access to:
 - 1) Simple cumulative descriptive statistics (gender, age distribution, blood type);
 - 2) Detailed cumulative descriptive statistics on a national level (e.g. 'Annual Report').
- National authorities of the Eurotransplant member states have access to data down to patient level for donors from their own country and recipients from their own country (including the corresponding donors), if needed to address a specific question within the framework of their supervising role as specified in national law or bilateral contracts.

Summary

		Registration	Donation	Transplantation	Follow-Up/ Outcome
Patient level		C	C	C	C
Centre level	Detailed	M	M	M	C
	Basic ¹	P	P	P	-
Country level		P	P	P	M

1 Simple cumulative descriptive statistics (gender, age distribution, blood type, primary disease)

C: Authorized user within the Centre / National Competent Authority

M: Individuals with access to the ET-Member site /Board/ Advisory Committees

P: General Public

Publication of ET-presentations on the Eurotransplant-website

Based on the above outlined general rules for data-presentation and data-delivery the following regulations apply:

- Presentations / slides containing personal identifiable patient data shall not be published on the Eurotransplant website.
- Presentations / slides containing centre-specific outcome data shall not be published on the Eurotransplant website.
- Presentations containing general country-specific / Eurotransplant-wide data may be published on the Eurotransplant public website.

The Board or the respective Advisory Committees can decide not to publish individual analyses / slides or whole presentations on the Eurotransplant website.

ANNEX 2: Procedure for requesting data for scientific research

The purpose of this document is to outline the procedure which has been established by Eurotransplant to manage external requests for data for scientific research.

How to send in a request

The requesting party shall send a written request for data accompanied with the study protocol to Eurotransplant. Both the request as well as the protocol should be in English.

Admission of a request

All written requests for data and/or analysis submitted to Eurotransplant, will be forwarded to the Eurotransplant request department.

The request department will review the request for completeness and determine the level of priority of the received requests. The request department will make an assessment on a case-to-case basis of the estimated processing time of the request. In relevant cases the request will be forwarded to the Eurotransplant Advisory Committee concerned for approval. Depending on the scope of the request, the turnaround time of handling the request can vary from days to more than a month.

Conditions for receiving data

The request department prepares a response to the requestor, approval or otherwise, with any conditions which may be attached to the use of data. The requesting party shall respect the conditions of each request.

The following are the conditions for receiving data from Eurotransplant:

- The data provided shall be specific for the purpose of the research project.
- Before the start and after ending the research project no data will be provided.
- The data made available to the requestor shall not be made available by the requestor to third parties without the approval of Eurotransplant.
- The researcher shall execute the study in compliance with the guidelines on Good Clinical Practice, guidelines on authorship and publication of the International Committee of Medical Journal Editors (www.ICMJE.org), the Eurotransplant Data policy and Disclosure policy.
- Before publication the requestor will be required to send the outcome of the research to the respective Advisory Committee of Eurotransplant for information, or, when appropriate (the author is informed beforehand) for approval before admission for publication.

Costs

In case of more complex responses a fee may be charged. Requestors will be provided beforehand with a written estimate.