



**ERN TRANSPLANTCHILD SOT&HSCT**  
**Pediatric transplantation in Children**

**STANDARD OPERATING PROCEDURE**  
**FOR PATIENTS' SUBCOMMITTEE**

Version August 2017

## SOP for Patients' Subcommittee

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| <b>Main changes</b>                            |                                       |
| Initial version                                |                                       |

## SOP for Patients' SubCommittee

### 1. Objective

The objective of this document is to establish the organization, roles, responsibilities and operational rules of the TransplantChild Patients' SubCommittee (here in after, PatientSC):

- To represent the voice of patients within the network to ensure the needs of people living with a paediatric transplantation are included in the strategic and operational delivery of the network;
- To create a bridge between the Network and the patient community, to, ultimately, improve the pre-transplant and transplant activities as well as post-transplant care;

### 2. Scope

This document applies to the governance and coordination structure required at this Committee. Thus, it applies to all:

- **The members** involved in this SubCommittee;
- **The related activities**, in compliance with Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, in which this SubCommittee is involved **and included within TransplantChild scope**.

### 3. Legal basis

- Art. 12(2) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
- Commission Delegated Decision (2014/286/EU) of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil.
- Commission Implementing decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks.

### 4. Abbreviations

**BoN:** Board of the Network

**EU:** European Union

**EOC:** Executive Operating Committee

**HCP:** Healthcare provider

**MS:** Member States of the European Union

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**PatientSC:** TransplantChild Patients' SubCommittee.

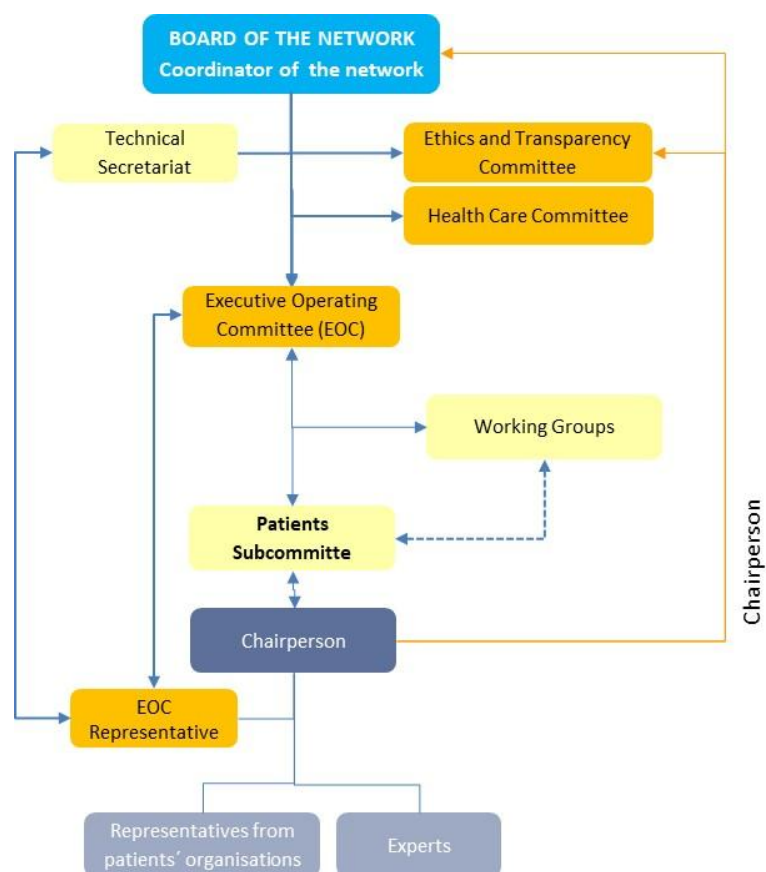
**SOP:** Standard Operating Procedure

**WG:** Working Groups

### 5. Governance and organisational structure of the SubCommittee

#### 5.1. Organisational structure

The organisational structure is depicted as follows:



### 6. Members, roles and responsibilities

#### 6.1. Composition

- Members:** the Patients Subcommittee is composed by one representative from different patients' organisations related to paediatric transplantation through Europe. All patients' organisations are invited to participate and become members of the Patients Subcommittee.

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Patients' organisations willing to be involved in this SubCommittee shall inform the coordinating centre in writing (e-mail to the Coordinator of the Network) including the name and contact details of the representative.

The EOC will approve the new patient organization involvement and the decision will be ratified by the BoN. Only officially accepted representatives are allowed to attend and participate in the SubCommittee activities.

The incorporation of new patient organizations will be communicated to the rest of the Subcommittee members and to BoN during their regular meetings.

A Patients' organization wishing to withdraw from the Patients Subcommittee shall send a written notification to the Coordinator of the Network and the Technical Secretariat.

- Chairperson: the Subcommittee members shall appoint one of the members for a period of two years. The Chairperson will be approved by the EOC and ratified by the BoN.
- Patients' Subcommittee Coordinator: one member of the EOC act as Coordinator to facilitate to the development of Subcommittee proposals as well as to ensure consistency in the development of the Network.
- When necessary, experts can be called to attend the Subcommittee meetings based on their experience, expertise and knowledge on the topic to be addressed.

### 6.2. Patients' Subcommittee responsibilities

The Patients Subcommittee is aimed at providing the framework to take into consideration patients and their families' voice and experience, by:

- Proposing, to the EOC, relevant issues to ensure patient involvement in the development of the Network in aspects such as:
  - Patient information, education and training activities for patients/families and professionals, good practice guidelines, treatment and care pathways for professionals' advice.
  - Research priorities to ensure that the network is informed by the needs of patients and families.
  - Ethical issues on the application of personal data rules, compliance of informed consent and patients' rights.
- Attending to the Working Groups meetings in which their presence is requested or in those in which the Subcommittee itself is part of as decided by the EOC.
- Acting as a member of the BoN and attending to the BoN meetings (Chairperson).
- Supporting the network with the dissemination of information and communication to the wider European patient community.
- Advising on ethical issues such as conflicts of interest.

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- Advising on management of complaints.
- Engaging with the appropriate patient communities for specific activities and projects.

### 6.3. Chairperson responsibilities

The representative of patients' organisations provides to the Network the point of view and information of patients and their families, by:

- Acting as representative of the Patients Subcommittee within the BoN, attending their meetings. If the Chairperson is not able to attend to one of the meeting he or she would designate another member of the PatientSC only for this meeting, who would represent the PatientSC.
- Attending to the EOC meetings, where required.
- Proposing to the EOC relevant issues to be addressed by the network.
- Asking for the EOC approval prior to the participation of any member of the PatientSC in events and/or forums to represent the network Reporting information and relevant results from the Patients Subcommittee (summary report).
- Identifying and recommend expert centres and other healthcare professionals that should join the ERN, either as a full member or an affiliated partner.
- Establishing relations with relevant specific patient organisations when necessary.
- Being part of the Ethics and Transparency Committee of the network, attending their meetings.

## 7. TransplantChild Patients' Committee Operational Rules

### 7.1. Meeting management

The Patients' SubCommittee members will agree on the relevant issues (included within the scope of the network) that need to be addressed in the network.

The Patients' Subcommittee representative will:

- Present the proposals to the EOC at its regular meetings.
- Setup the topics on the agenda.
- Establish, with the support of the EOC representative, the planning for its development (as far as possible).

At least one week in advance, supporting documents and agenda to be discussed during the meeting of the PatientSC shall be developed and made available to all the attendees.

The documents / systematics / methodologies developed by the Patients' Subcommittee will be presented to the BoN for their approval prior to their use and / or dissemination throughout the Network and interested parties.

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### 7.2. Decision-making

The voting system shall be one vote per member of the SubCommittee. As far as possible, Patients' SubCommittee decisions shall be made under consensus. However, when consensus cannot be reached the following order will be followed:

1. Absolute majority (half of the votes plus one);
2. Simple majority;
3. In case of draw, the EOC representative will make the final decision.

The Technical Secretariat shall sum up the conclusions and decisions of the meeting in the minutes, including related actions, responsible and deadlines, if any.

### 7.3. Representation and dissemination activities

The participation of Patients' SubCommittee members in forums events and training, communication or discussion activities, on behalf of the Network, must be communicated and validated by the EOC prior to the corresponding event. The aspects addressed will be reported to the EOC for dissemination throughout the Network and stakeholders by the established mechanisms for that purpose.

Patients' SubCommittee dissemination activities will be carry out in line with the ERN Communication Plan so that they must be approved by the EOC.

In addition, the Annual Activity Report (including the Patients' SubCommittee activities) will be disseminated through TransplantChild website and all the members of the Network and affiliated partners will be informed accordingly.

### 7.4. Patients' Committee monitoring and follow-up

At least three (3) times a year the Patients' SubCommittee representative will:

- Prepare a summary report of its activities.
- Send this report to the EOC for its integration into the Periodical Follow up Activity Report.
- Present the report to the BoN during their regular meetings.

The report will include:

- Planned activities and other foreseen actions for the period and their status.
- Issues arose during the period and the related actions and results.
- Activities carried out.
- Outcome indicator results (if appropriate).
- Incorporation of new patients' organisations proposals.

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- Dissemination activities.
- Other proposals.

The BoN will carry out an analysis of the report. As a consequence new actions can be established. Any related conclusion or decision-making will be recorded in the minutes of the meeting.

### 7.5. Confidentiality

The members of this Subcommittee undertake that any information or documentation that TransplantChild will deliver to or to which they have access for any reason, directly or indirectly, will be used only within the scope of this Subcommittee.

Consequently, it may not provide to third parties, reproduce without authorization or use for other purposes than foreseen the information obtained in the exercise of its functions within the Subcommittee.

## 8. SOP entry into force, revision and amendments

This SOP will enter into force once it is approved by the EOC and ratified by the BoN and shall be reviewed and updated on an annual basis.

However, any member of both the BoN and the Patients' SubCommittee can propose amendments to this SOP with justified reasons.

In this sense, any proposal shall be accompanied by an explanatory report on the causes and extent of the proposed amendment. The proposals will be studied by the EOC and then presented by the Coordinator of the Network at the regular meetings of the BoN and the decisions and agreements will be recorded in the minutes of the meeting. Following, the amendment of the SOP is under the Coordinator of the Network responsibility.

Any amendment of this SOP shall be communicated to the HCPs members of the Network, uploaded, and disseminated through TransplantChild website by the Coordinating centre. Other dissemination activities/tools may also be used in line with the ERN Communication Plan.

**Each member of the SubCommittee shall comply with the rules and principles set forth in this SOP.**