T r a n s l a t i o n

GPN – Gesellschaft für Pädiatrische Nephrologie
(Society for Paediatric Nephrology)-
Working Group Kidney Transplantation

Registry
‘Kidney transplantation in children and adolescents’

founded and operated on behalf of the Society for Paediatric Nephrology (GPN)

Statute and Rules of Procedure

Version of February 18, 2010
Updated on September 15, 2014

1. Preamble

On behalf of the GPN (Society for Paediatric Nephrology), the **C**ooperative **E**uropean Paediatric **R**enal **T**ranspl**A**nt **I**nitiative (CERTAIN) Registry was founded by the study group 'Kidney transplantation in children and adolescents' of the GPN. Purpose of this registry is to support and enable scientific evaluations and quality assurance within the area of paediatric kidney transplantation. For this purpose, relevant data will be preferably gathered regularly of all paediatric patients with renal transplants in Europe, especially, within the area of the GPN (Germany, Austria, Switzerland) and other associated specialized societies or those interested in a cooperation, respectively.

2. Aims and Tasks

The main goal of the CERTAIN Registry is to regularly gather clinical data of all paediatric recipients of renal transplants within the GPN and associated specialized societies in Europe, if possible. This will contribute to improving academic research and quality assurance in this field.

3. Members and Committees

3.1 Members / Participating Centers

Each center in Europe which follows up paediatric patients with renal transplants may contribute data to the registry. Each contributing center is also a member of CERTAIN. All members are obliged to perform a regular and careful data input.
Members of CERTAIN may request an updated extract from the database of those data supplied by them at any given time. If a member wants to evaluate all available data, the consent of the Steering Committee is required.
Each member has to assume responsibility for observation of data protection regulations.

3.2 Member assembly

The members meet once or twice per annum either within the frame of the Annual Meeting of the GPN and/or within the frame of the Meeting of the 'Study group for kidney transplantation in children and adolescents'.
The member assembly decides about all essential organizational and strategic matters regarding the CERTAIN Registry. As far as membership of the registry is concerned, all members are bound to the decisions made by the member assembly. The registry center is bound to decisions made by the member assembly.
The member assembly has to vote at least once annually on the following items:

(1) Approval of the minutes of the last meeting
(2) Support of the Steering Committee
(3) Support of the Registry Center
(4) Amendments regarding statute and rules of procedure

(5) Discussion of and decision on pending questions with respect to data evaluations

Based on its independent decision, each member (center) sends up to three delegates who are eligible to vote to the member assembly. Each member (center) is entitled to delegate additional participants who are not eligible to vote.

Each vote requires the specified majority. If no necessary majority has been specified, the simple majority of those members present at the meeting and eligible to vote is sufficient.

All votes – if not otherwise specified– are casted publicly by hand signal.

The member assemblies are organized by the Registry Center.

Minutes are taken on occasion of the member assembly. The minutes are prepared by the Registry Center and made available to all members. They are considered preliminarily approved within two weeks after their publication if the Registry Center has not received an explicit and justified rejection by any member. The explanatory statement must also state why the minutes should not be approved as preliminary until the next member assembly takes place. The final approval is obtained by a simple majority of those members eligible to vote on occasion of the next member assembly.

3.3. Steering Committee

The CERTAIN Steering Committee consists of one member each of those participating centers which during the 12 months prior to the respective meeting performed active patient data input into the Registry. Each center determines this member independently. The chairman of the study group kidney transplantation of the GPN, his deputy and a representative of the Registry Center are members of the Steering Committee by virtue of office. In case of vote equality, the vote of the Registry Centre decides.

The task of the Steering Committees is to continuously represent the interests of the CERTAIN Registry. Among these, decisions on submitted applications for evaluation of extracts from the overall database are of special importance. Applications for evaluation of data will be discussed and decided on occasion of the next member assembly, if possible; in case of urgent applications, decisions will be made via a voting system made available by Registry Centre. Eventually, the decisions have to be justified/discussed by the members of the Steering Committee on occasion of the member assembly.

3.4. Registry Center

The CERTAIN Registry has the following tasks:

(1) The Registry Center in Heidelberg has the task to enable data input via a database with internet access. The database and the presence in the internet have to be in line with all relevant laws and regulations. Furthermore, the database and the internet presence – as far as data input is concerned – have to warrant international standards analogous to clinical studies,

especially compliance to Good Clinical Practice (GCP). The functionality of the database is described in a special section attached as addendum and part of this as appendix statute.

(2) Upon request, the Registry Center will provide access to the centre's own data in a structured manner.

(3) The Registry Center will provide members with extracts of the overall database in order to enable scientific evaluations if approved by the Steering Committee or the member assembly. The Registry Center offers the possibility of taking over parts of the evaluations.

(4) The Registry Center will prepare the member assemblies and the preliminary minutes.

3.5. Patronage

The CERTAIN Registry will appoint a patron who – by his/her bond to the interests of paediatric kidney transplantation, his/her personal and public integrity and his/her high profile is in a position to effectively promote the registry.

4. Applications for evaluation of data and publications

4.1. Applications for evaluation of data

Each application for evaluation of an extract of the overall database is based on a written project layout supplying the following information:

a) Title of the project
b) Background (rationale of the evaluation, own and external preliminary work)
c) Question/problem enunciated as scientific hypothesis
d) Method (statistical design)
e) Information on participating individuals
f) Information on time frame conditions
g) Information on planned publication of the data (congresses, publication, authorship)

Basically, the layout should be set up in such a manner as to distinctly meet the requirements for approval as scientific publication. It may be submitted anytime.
Scientific evaluations should primarily be prepared and coordinated by members. In case of applications from external individuals, institutions or pharmaceutical companies the Steering Committee will decide.

4.2. Evaluation of the project layouts

Proposals for new evaluations will be presented to the Steering Committee or the member assembly (either directly or – if so decided by the Steering Committee - via an application submitted to the Steering Committee). In case of rejection, the applicant may ask for a resolution via the executive board of the GPN.

4.3. Accepted project layouts

Following acceptance of the project layout, the applicant will provide information within four weeks as to when the results of the evaluations will be available and in which form. Upon acceptance of the project layout, no second investigation on the same subject can be accepted. If the results are not available after three months following the planned date, the project is considered discontinued and can be turned over to a new applicant. The previous applicant should make available his preliminary work to the new applicant or cooperate with him, if possible.
The project with the planned timeframe is available on the homepage. The applicant will receive an extract of the database which contains the data – partially agminated – required for evaluations according to the project layout.

4.3. Publications and authorship

Besides quality assurance, publications and other scientific projects are to be supported by the CERTAIN Registry. The members generally agree to the use of the data for publication purposes.
The order in which the authors are listed depends mainly on the type of publication (case histories, review articles, project evaluations) and the degree of contribution by the participating parties. In case of case histories, the treating medical centers should always be considered. The initiative may also be started by the treating medical center. Review articles generally do not contain any new, i.e. unpublished results. In this case, the first author or the senior author designates the co-authors according to the degree of their contributions.
Basically, all those who contributed essentially to the conception and planning or analysis and interpretation of data, as well as to the wording of the manuscript, respectively, and who agreed to its publication should be part of the list of authors. Providing data on documented patients for a study/project does not necessarily result in co-authorship. In all publications on study/project questions, all members will be listed in the addendum.
As far as listing of authors is concerned, the primary author is generally the one who has prepared the manuscript. The place of the last author may be claimed by the study/project leader if he is not already first author. If several study/project leaders participated in a study, they will agree – according to the extent of their contribution – on the last author. The remaining authors are nominated by the participating study/project leaders and listed in order. In general, the corresponding author is the main responsible project leader.
In case of disagreements regarding authorship, the Steering Committee will decide.

5. Miscellaneous, final conclusions

5.1 Change in rules of procedure /statute

Changes regarding the rules of procedure are requested by the members and decided by the member assembly. Changes in the statute require two-thirds of the votes of all present representatives eligible to vote.

5.2. Safeguarding clause

Should some of the rules of this statute/rules of procedure be invalid due to national or supranational laws/regulations, the other rules remain unaffected by this.

5.3. Effective date

This updated statute and rules of procedure are effective by approval on occasion of the meeting of the ‘Study group kidney transplantation in children and adolescents’ on December 5/6, 2014.