IMPLEMENTATION OF A NOVEL WEB-BASED REGISTRY FOR PEDIATRIC KIDNEY TRANSPLANTATION IN CENTRAL EUROPE – THE CERTAIN REGISTRY

www.certain-registry.eu

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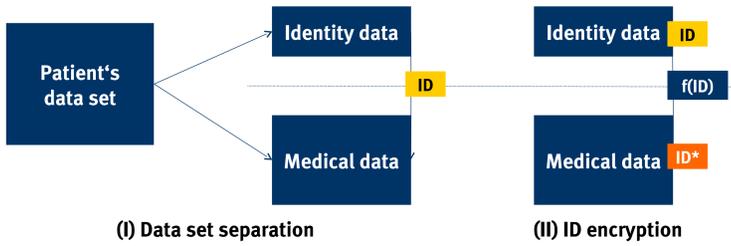
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Motivation

Long-term data collection for pediatric renal transplant (RTx) recipients is crucial for clinical research, quality assurance and improved patient care, yet a proper registry in central Europe is lacking. Therefore, the **G**erman **P**aediatric **N**ephrology Association (**GPN**) decided in 2009 to initiate such a registry, which was named **CERTAIN** (**C**ooperative **E**uropean Paediatric **R**enal **T**ranspl**A**nt **IN**itiative) Registry.

Privacy by design & architecture

Patient's data privacy and security have been considered from the beginning and therefore had substantial impact on the system design. The main concept, the patient's data set's separation into identity and medical sub-data sets with separated processing and storage and further ID encryption, is based on the work of the German Technology, Methods and Infrastructure for Networked Medical Research organization (**TMF** www.tmf-ev.de). CERTAIN's data privacy concept has been approved both by the TMF and the state commissioner for data protection in Baden-Württemberg, Germany.

(I) Data set separation   **(II) ID encryption**

CERTAIN registry's architecture assures the data set distribution defined by the privacy concept on all levels of the system. The consolidation of patient's data is possible only on the client when used by a user with adequate rights. All servers are hosted in independent data centers.

Technology

The system is developed using an open source technology stack from the Java™ ecosystem. All relevant functionalities can be accessed comfortably without any extra configuration or software installation via the CERTAIN web application – a rich internet application offering a desktop-like user experience developed using the Google Web Toolkit (GWT). The server-side is based on standard Java server technologies and MySQL™ as the database. Complete network traffic between the client and the servers as well between the servers themselves is encrypted using TLS/SSL (Transport Layer Security / Secure Sockets Layer).

Data interchange

To minimize manual data input and workload in the participating centers, bidirectional and unidirectional data interchange with other systems, such as the Collaborative Transplant Study (CTS) and the ESPN/ERA-EDTA registry has been realized. Cooperations with the organ allocation institution Eurotransplant and the kidney centers network (KfH) in Germany have been established; the automatic data interchange providing recipient and donor data from Euro-transplant and data transfer directly from the KfH information system is being developed.

Features

The web application enables not only data entry with integrated automatic data validation, but also manual two-step quality control of the provided data set. The system offers also a patient chart view of the stored data and automatic calculation and visualization of relevant clinical values (e.g. GFR acc. Schwartz 2009, electronic growth charts for all relevant anthropometric data) and therefore can be useful during the clinical routine.

Status & Development

The system went online in October, 2010. After a test phase till February, 2011 in Heidelberg and Munich, the registry has been made available to all interested pediatric transplantation centers across Europe. Currently there are 19 participating centers from Germany, Austria and Poland. The registry aroused quickly interest in other countries/centers such as Turkey, which will join the CERTAIN community in the near feature.

Research topics

- Factors influencing patient and transplant survival
- Immunological and non-immunological causes of short- and long-term renal allograft loss
- Effects of immunosuppressants and drug combinations
- Short- and long-term toxicity of immunosuppressive drugs
- Cardiovascular co-morbidity
- Infectious complications (opportunistic infections, transplant pyelonephritis etc.) and anti-infective agents
- Incidence of post-transplant malignancies
- Hospitalization
- Growth and pubertal development
- Psychosocial development
- Adherence

Steering committee

Steering committee members are responsible for the scientific decisions regarding the registry. Each participating transplant center can designate one person to participate in this committee and has therefore substantial impact on the project.
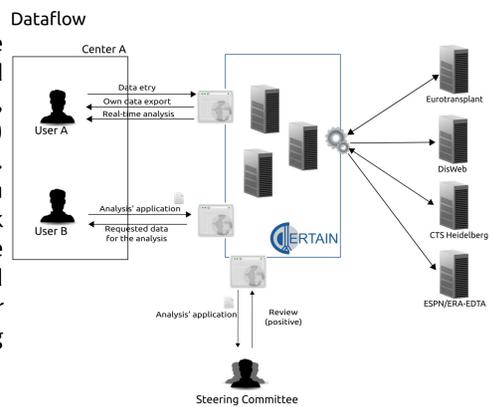
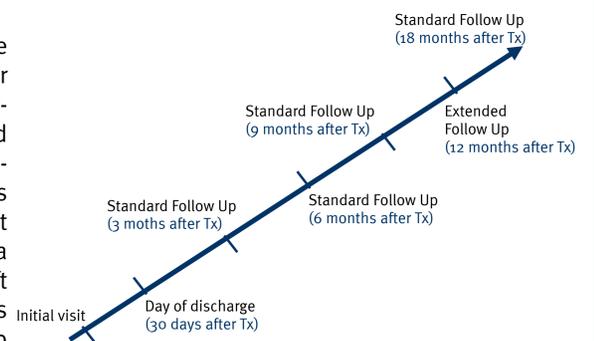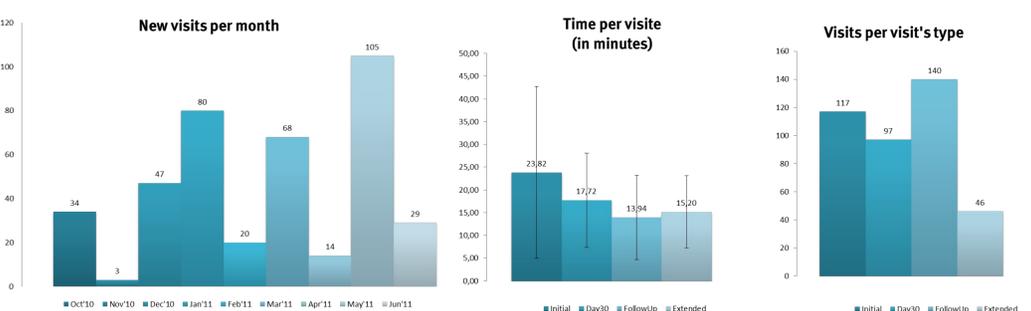|	Center	Steering Committee Member		Center	Steering Committee Member
1	Berlin	Querfeld	12	Leipzig	Wygoda
2	Celle	Kirschstein	13	Marburg	Klaus
3	Cologne	Hoppe	14	Memmingen	Fehrenbach
4	Frankfurt	Schröder	15	Muenster	Konrad
5	Essen	Hoyer	16	Munich	Weber
6	Freiburg	Pohl	17	Prag	Seeman
7	Hamburg	Kemper	18	Rostock	Wigger
8	Hannover	Pape	19	Stuttgart	Leichter
9	Heidelberg	Tönshoff	20	Tuebingen	Amon
10	Innsbruck	Jungraithmayr	21	Ulm	Beringer
11	Jena	John	22	Warsaw	Grenda

Reimbursement & data ownership

The participating centers will be reimbursed for their work accordingly to the amount of data they provide:

- **75 EUR per patient for the 1st year**
  - for each new patient including all follow ups for the first year post-transplant
- **20 EUR per patient/year for the consecutive years**
  - for all patient's follow ups in the following year

The data provided by the participating center is the property of this center and can therefore be exported from the system and used by the center at any given time. The same rules apply on a country level: Each country can request his data for country-wide analyses. The data will be provided without any review process regarding the planned analysis. In case of an analysis based on the entire registry population, a positive vote of the steering committee is required. The publication rules are defined by the CERTAIN Registry's "Rules of Procedure" (see website for details).

Data set & entry schedule

Patients are to be enrolled into the registry after having received their first kidney transplant. Five follow-up visits are to be documented during the first year post-transplant, thereafter 2 follow-ups per year. The patient data set consists of well-defined data forms (e.g. donor data, graft status) and continuous entries such as medication and lab values, which can be added to each visit without any restrictions.