

MP3-19

Establishment of a German Research Network for Congenital Heart Defects

*Bauer U. M. M. (1), Pickardt T. (1), Asfour B. (2, 3), Baumgartner H. (3), Bahlmann J. (2, 3), Berger F. (2), Breithardt G. (2), De Haan F. (2, 3), Hetzer R. (2, 3), Hofbeck M. (2), Kececioglu D. (3), Klaassen S. (2), Kramer H. H. (2), Nürnberg J.H. (2), Sarikouch S. (2), Schmaltz A. A. (2, 3), Abdul-Khaliq H. (2); Competence Network for Congenital Heart Defects
CNCHD Central Office Berlin, Germany (1),
CNCHD Steering Committee (2)
National Register for Congenital Heart Defects Management Board (3)*

Objectives

The Competence Network for Congenital Heart Defects (CNCHD) was established to facilitate multicentre medical and socio-medical research in the field of congenital heart defects (CHD), which is intended to lead to an improvement of health care and out-come for this relatively new and continuously rising patient group. Due to the characteristics of this disease (high variability of morphological heart defects, chronic illness), the network infrastructure has to overcome specific challenges such as research in underage patients or the implementation of a legal framework for long-term storage of data and biomaterial.

Methods and Results

The CNCHD succeeded in implementing a sustainable research infrastructure involving all important stakeholders throughout Germany. The infrastructure is built around the non-profit registered association National Register for Congenital Heart Defects (NRCHD e. V.) that provides a dynamic and flexible IT-platform for different types of database-systems for register studies and a multicentre biorepository that collects blood-derived DNA and cardiac tissue from heart surgery. Thanks to central patient and ID management, data of different formats and recorded at different times can be clearly assigned to respective patients, thus allowing multicentre and longitudinal investigations. Electronic case report forms and remote data entry are used to centrally collect and store the data. Specific role based access rights management can be implemented for decentralised data entry by different users (physicians, researchers, documentation staff, monitors, sample laboratory etc.), e.g. within the scope of multicentre studies. This enables the integration of national and international research units, which is of particular importance with regard to recruiting new cooperation partners.

In January 2014 the National Register comprises 46.333 participants. The majority (64 %) is underage, sex is evenly distributed. Simple heart lesions represent 38 %, moderate 52 %, and severe/complex 10 %. The DNA collection currently comprises samples from approximately 3000 participants covering a wide range of CHD phenotypes. The collection includes also trios (patient + unaffected parents) and families with more than one affected member.

Conclusions

The CNCHD provides a comprehensive basis for high-level research in the field of CHD with high standards of ethics, data privacy, IT management and sample logistics.