



Patient information and declaration of consent to participation in a centralised collection of data for the purpose of national quality assurance (QS) for the treatment of congenital heart defects

Dear Patient,
Dear Parents,

As expert associations, the German Society for Paediatric Cardiology (DGPK) and the German Society for Thoracic and Cardiovascular Surgery (DGTHG) would like to carry out a quality assurance measure for the treatment of all those patients with a congenital heart defect. For this purpose, data on all the heart operations performed and all the therapeutic cardiac catheter interventions as well as data on the follow-up examination(s) are to be collected in a database and evaluated by an independent expert commission.

The aim of this measure is to identify potential for improvement and to ensure quality in the treatment of congenital heart defects in the long term. In addition, the data collected in Germany are to be compared with those from international data collections.

The method was tested for its feasibility in a pilot phase between June 2008 and December 2010. The ethics commissions responsible approved the project.

In order to ensure that the nationwide data evaluation runs smoothly, the information collected will be saved and processed at a central location. The National Registry for Congenital Heart Defects association in Berlin was selected for this part of the task because it has a recognised database system and years of experience in the field of congenital heart defects (www.kompetenznetzahf.de).

For this quality assurance project, the National Registry for Congenital Heart Defects has set up an independent database in which the treatment data will be separately collected and saved. This data will comprise all the medical data in connection with each intervention as well as the medical findings of follow-up examinations. The data will be entered directly by the physicians/clinics giving treatment via a secure internet connection.

The data will be evaluated by an independent expert body, which will conduct an assessment jointly with DGPK and DGTHG on the basis of specified quality criteria.

The national quality assurance project only makes sense if data are gathered on as many interventions as possible. This is why we kindly ask you to take part.

If you have read the above, fully understand the contents and would like to take part in the centralised collection of data for the purpose of quality assurance, please give your consent to our saving and processing the necessary medical treatment data of the intervention carried out on you/your child on the enclosed declaration of consent.

We thank you for your cooperation and remain,

Sincerely yours

The Project Team



Information on data protection

The collection of data is intended for the project named above. All data are saved and processed in accordance with the data protection concept of the National Registry for Congenital Heart Defects, which has been examined by the data protection officers of the states of Germany. The data are saved electronically in pseudonymised form (i.e. encrypted) and are protected against access by third parties. The evaluation and publication of the data for statistical purposes is carried out anonymously, i.e. without any reference to you/your child personally.

You will not suffer any disadvantages by not taking part. Similarly, any approval you have already given can be withdrawn at any time with no need to give reasons. You may demand information on the data saved on you or demand that such data is deleted at any time.

The National Registry for Congenital Heart Defects is responsible for data processing (the address and telephone number is provided at the end of this information sheet).

Please do not hesitate to contact us if you should have any further questions. To do so, either speak with the physician giving you this information or contact the National Registry for Congenital Heart Defects directly:

Investigating physician (stamp):

Contact at National Registry for Congenital Heart Defects:

Dr. med. Ulrike Bauer
Managing Director
Competence Network for Congenital Heart Defects and
National Registry for Congenital Heart Defects
Augustenburger Platz 1
13353 Berlin, Germany
Tel.: +49 30/4593-7276
Fax: +49 30/4593-7278
E-mail: ubauer@kompetenznetz-ahf.de

Please find the form for your declaration of consent on the next page.



Patient information and declaration of consent to participation in a centralised collection of data for the purpose of national quality assurance (QS) for the treatment of congenital heart defects

Personal details of the patient

Surname: _____

First name: _____

Date of birth: _____

I consent to taking part in the project named above on a voluntary basis. I was provided clear, detailed information about the nature, significance, risks and implications of the project in a personal discussion. I had the opportunity of having an advisory consultation. All of my questions were answered to my satisfaction and I may ask new questions at any time. Furthermore, I have read and understood the text providing details of the study.

I had sufficient time to make a decision. I am aware that I can withdraw my consent to take part in the study (verbally or in writing) at any time without giving any reasons and without suffering any disadvantages for doing so.

Declaration of consent to data processing

I have understood and consent to my child's health data relating to the study being collected in pseudonymised form (i.e. encoded without stating any name, address, initials or similar), saved on storage media and evaluated by the party commissioning the study. The data are disclosed to third parties and published solely in anonymised form, i.e. the data will not be able to identify me/my child.

Each collection of data which exceeds this scope requires an additional declaration of consent.

I have received, read and understood a copy of the information on the study and the declaration of consent.

Place, date

Signature of patient/carer

Place, date

Signature of 2nd carer*

Place, date

Signature/stamp of the physician giving information

* The signature of both parents or guardians is required for patients who are minors.