Patient Information

and

Informed Consent

A co-operation of the following organisations

Deutsche Hämophiliegesellschaft e. V. (DHG; German Haemophilia Association)

Interessengemeinschaft Hämophiler e. V. (IGH; Interest Group of Haemophiliacs)

Gesellschaft für Thrombose- und Hämostaseforschung e. V. (GTH; Society for Thrombosis and Haemostasis Research)

Paul-Ehrlich-Institut (PEI; Federal Institute for Vaccines and Biomedicines)
Dear Sir or Madam,

Your doctor has provided you with patient information and advised you of the possibility to participate in the German Haemophilia Registry (Deutsches Hämophilieregister) (dhr).

We would like to give you some important information, which you will need to know in order to decide whether you wish to participate; please read carefully.

Your doctor will also tell you about the DHR in person. Please do not hesitate to ask if you need more information or if there is anything you do not understand.

Whether you will participate in the DHR remains entirely your own decision. We would be very happy if you joined in.

Your DHR-Team

About us

We, i.e the participating institutions:

- Paul-Ehrlich-Institut (PEI) in its function as the senior federal authority,
- Gesellschaft für Thrombose- und Hämostaseforschung e. V. (GTH; Society for Thrombosis and Haemostasis Research) in its function as scientific society,

and the following two patient organisations are involved as representatives of the patients’ interests:

- Deutsche Hämophiliegesellschaft zur Bekämpfung von Blutungskrankheiten e. V. (DHG; German Haemophilia Association for Combating Bleeding Disorders) and
- Interessengemeinschaft Hämophiler e. V. (IGH; Interest Group of Haemophiliacs).

Supported by the Federal Health Ministry (Bundesministerium für Gesundheit; BMG), we all have a common goal: to improve the treatment with blood products and the quality of life for patients with blood coagulation disorders — haemophilia A or B, von Willebrand’s disease etc.

The DHR – its role and its purpose

The German Haemophilia Registry is an online database (operated at the Paul-Ehrlich-Institut) for the storage and evaluation of pseudonymised data (see below) of patients with a blood coagulation disorder.

The DHR is designed ...

- to support the best possible provision of blood products for each patient. This is very important, also since blood products cannot be stored indefinitely, like other medicinal products, and since they are not available in unlimited amounts.

The DHR is designed ...

- to promote scientific clinical research for better treatment of your disease. We need to collect data from many patients to obtain a meaningful evaluation and important findings that go beyond the experience of the individual patient and doctor. To compare data obtained over time, we keep all data — both old and new — for an indefinite period.

What do we hope to get from this research? In short: We expect to find better concepts for prevention (prophylaxis), for appropriate care for operations and lesions, as well as for recording and treating complications (e.g. inhibitors).

The DHR makes it easier …
• for the Paul-Ehrlich-Institut, to collect data on the availability of products for the treatment of haemophilia, a requirement which the PEI is obliged to fulfil in compliance with Section 21 of the German Transfusion Act (Transfusionsgesetz, TFG).  

We can explain this as follows: Since 1998, the PEI, as the senior Federal Authority, has been obliged to compile an anonymised report which, among other things, includes statements on the consumption of coagulation factors and the number of patients treated with these products. Even if a patient does not participate in the collection of personal data in the DHR, every doctor must report the number of patients treated and the total consumption of blood products to the PEI per year in the form of an anonymised collective report. Your participation in the collection of personal data for the DHR, however, will both make it easier for your doctor to fulfil his reporting obligation, and for the PEI to fulfil its obligation to report.

Your decision – its effects and its significance for us

Your decision to participate in the German Haemophilia Registry constitutes an active contribution to improving your own supply of blood products and your treatment situation, as well as that of all other patients on a long-term basis. Your participation is also of great significance for us since the basis for the data – and only pseudonymised data is reported – is an important factor in obtaining results with a high information value. 

The fact is: no data – no research. However, patients’ rights have priority (see data protection).

What is pseudonymised data?

Pseudonyms are aliases, which prevent an individual from being identified. The fact that we only work with pseudonymised data means: (1) Your name, your complete date of birth and your address will not be transmitted to the DHR at any time. (2) The details communicated by your doctor together with your diagnostic and therapeutic data include the patient’s number consisting of your insurance number and the code for your health insurance company. Since the patient number is a piece of information that can be referred to a person, it will be stored at the Paul-Ehrlich-Institut only during the process of calculating the pseudonym (temporarily). Thus, the patient number functions in the same way as a key to the pseudonym; the pseudonym, however, is not a key to the patient number. When the pseudonym has been calculated with the aid of the patient number, the patient number is erased.

Why can the data not be anonymised?

If the data were completely anonymised, it would not be possible to record and assign them on a continuous basis. Only a pseudonym makes it possible to assign the data reported by your doctor to the data already available in an unambiguous manner, whenever new data is added within the DHR. Only on doing this, can reliable statements be made on the number of patients to be treated and the course of the disease, i.e. only thus can the aim of the DHR, to create a major database with high information value, be attained.

Which of my data will be transmitted?

Your doctor will transmit profile data and medical (i.e. diagnostic and therapeutic) data online.

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1 Excerpt from Section 21 TFG:

«(1) The entities responsible for donation facilities, the pharmaceutical entrepreneurs and the health care facilities shall annually report to the competent higher federal authority the figures indicating the scope of the collection of blood and blood components, the production, import and export and quantities used of blood products and plasma proteins as defined in section 14 paragraph 1 as well as the number of the treated persons with congenital haemostasis disorders. The reports shall be submitted after the end of the calendar year, at the latest by 1 March of the following year.

(2) The competent higher federal authority shall compile the data that have been rendered anonymous, in a report and publish it. It shall handle any data specific to the reporting entity on a strictly confidential basis.»
Patient Information

Profile data …
…includes your sex, month and year of birth and the first two digits of your residential post code. The profile data is assigned to the pseudonym. It is required for scientific evaluation of the data and to form patient groups.

Diagnostic data …
…includes type of disorder, residual activity - in case of Willebrand's disease AG (%), RCo (%), CB (%), VIII:c (%), epinephrine (s) and ADP (s) - as well as anamnestic data.
Anamnestic data includes date of diagnosis, date of first bleeding event and its localisation, date of the first administration of the factor, and type of medicinal product (plasmatic or recombinant), possible change in the type of medicinal product, possible administration of the factor before the first bleeding, whether treatment with DDAVP was attempted, whether this treatment was successful, whether the factor was administered before the patient’s data was recorded in the DHR, whether the disease is congenital or acquired, whether another family member has coagulation disorders, whether a titre determination was performed – if yes, when and for what reason – and whether the patient was given special treatment of the inhibitor.

Therapeutic data …
…is reported to the DHR on a regular basis – at least once a year. It includes the consumption of coagulation factors, the therapy regimen (on-demand or prophylaxis), name of medicinal product, exposure days (optional), number of bleeding events requiring treatment in the reporting period, occurring inhibitors, if any (in addition to the % value of Bethesda units/ml, the date of determination is also indicated here), and the performance of immune tolerance induction, if done.

In the event of immune tolerance induction, the data recorded also includes the treatment period, the dose administered to you per kg bodyweight (optional), your bodyweight together with the product used, and whether you received products for immune suppression.

Other data recorded includes whether this treatment was successful, otherwise, your current titre is given. If in-patient treatment was required due to bleeding (indicating the localisation), surgery or accidents, this is indicated together with the number of days of in-patient treatment per year. Out-patient surgery, if applicable, will also be recorded.

Will further data be recorded, and who decides on that?
It is planned to record further medical data in connection with a coagulation disorder. Examples include: Adverse reactions of the products administered, joint status, and infections. This information and other requests require authorisation by the Committee of the DHR, consisting of two representatives of the institution/organisations that participate in the DHR.

In this case, too, the patient organisations will represent your interests, and guarantee that only data is recorded, which is useful for research and beneficial for your therapy.

You can always obtain all queries from your doctor, or find them on the PEI homepage (www.pei.de). In the event that you do not agree with the data currently recorded, you can withdraw your consent to recording the data at any time.

Data protection
To preserve your personal rights and to guarantee data protection, the concept of the DHR was submitted to the data protection representatives of the Länder (Federal German States) and the Federal German Government for verification and was accepted.

In an assessment procedure at the PEI, the federal data protection representative verified and confirmed the proper implementation of data protection measures.

Am I obliged to participate in the DHR?
No. You are not obliged to participate in the DHR, neither from the legal nor any other point of view. You will not encounter any disadvantages if you decide against participation in the
DHR – neither regarding your treatment nor concerning the relationship with your doctor. In »participation with the DHR«, we always refer to the recording of your personal profile data and your medical data. If you decide to participate, you will make an important contribution to the further optimisation of supply and treatment as well as new research projects in the field of haemophilia A and B, von Willebrand’s disease, and other coagulation disorders. You are also making an active contribution to improving the quality of life of all those affected.

What must I do to participate in the DHR?

We would be very pleased if we are able to convince you of the necessity, meaning, and purpose, as well as the advantages of the German Haemophilia Registry, and if you are willing to participate.

Talk to your doctor and ask to be included in the DHR. For your participation, we need your full consent for the use of your personal data to the extent described above. It includes a release from medical secrecy for your doctor for data listed in this patient information, and exclusively refers the transmission of your data to the DHR.

The informed consent handed out to you remains with your doctor; you receive a copy.

What is important if I do participate?

If you decide to participate, your doctor will provide you with a printout of your non-variable data as soon as he enters your data. This includes data on your primary disorder, residual activity, and your anamnesis.

Please keep this printout carefully. Should you change your treating doctor, submit this printout to him. The new doctor can enter this data again as he is not able to see it (explained below). The Registry will match your data in the database, if entered by different doctors. This is significant for the continuation of recording and evaluation.

Can minors participate as well?

Of course, minors can and should participate in the DHR. To guarantee the full protection of minors, the DHR requires the signature of all legal representatives of the minor (generally the parents) in the separate »informed consent (parents)« declaration. Minors who can judge the significance and the implications of their participation in the DHR are required to sign as well. Whether a minor is able to do so has to be decided individually. For the protection of minors, both the minors themselves and their legal representatives must give their consent to the participation in the DHR. In case of disagreement, the minor may not participate in the DHR.

Who will transmit and edit my data?

The DHR will grant access rights to the data only to participating doctors (with user ID and password). Only these doctors can enter their patients’ data. It will not be possible for a doctor to view data of patients he is not treating. Therefore, if you participate in the DHR, your doctor has two means of viewing your data: in his own records or through the DHR.

To protect the DHR from unauthorised access, the Paul-Ehrlich-Institut has installed extensive protection measures. To secure data quality, e.g. to find errors in the data entry, the staff members at the PEI in charge of the DHR will be granted access to your medical data for a limited period of time after receiving permission from your treating doctor. They will be granted read-only access.

It is very important to know that by accessing the data, the staff members are unable to draw any information to your identity, since neither the profile data (sex, month and year of birth, and the first two digits of your post code) nor is any other identifying data indicated.

Who will process my data?

If scientists and research institutes wish to evaluate data for the purpose of further research, they will be obliged to make a written application to the Committee of the DHR (see above).

The application must include a detailed description of the study project, the data required, and
guarantee data protection. The committee will decide whether to accept the application for the use of the pseudonymised data for the research and scientific purpose.

The research activities must agree with the aims of the DHR or must be beneficial to them. If this is the case, the data requested will be exported from the DHR by a PEI staff member without transmitting the pseudonyms (i.e. anonymously), verified by the committee, and released. The data will only be available to the applicant after its release. Announcements will be reviewed by the Committee of the DHR before publication.

The use of anonymised data is also subject to top priority data protection.

Who is responsible for my data?

The Paul-Ehrlich-Institut is the competent authority for the data stored in the DHR from the point of view of the data protection law. You can contact the PEI whenever you have any questions concerning the DHR. However, the PEI cannot give you any information on your own data, since, as we have explained above, the DHR only contains pseudonyms, which are not assigned to an individual, and this includes you as a person raising a question in your own interest. Only your doctor can answer questions concerning your data. Your doctor can provide you with the information on the data stored by him at any time. You are entitled to have errors in your data corrected.

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Please also visit the website of the Paul-Ehrlich-Institut for further information on the DHR: http://www.pei.de.

How do I withdraw my consent?

You will remain in control of your data. If you no longer wish to participate in the DHR, despite your declaration of consent, you must inform your doctor in writing of your withdrawal at any time. You do not have to state any reasons. In addition, no disadvantages will arise for you concerning your treatment or your relationship with your doctor. No further personal data will be recorded. The data recorded on you up to the time of your withdrawal will be anonymised entirely, i.e. the pseudonym will be deleted and replaced by a random number. This number is stored exclusively in the Registry and cannot be communicated to anybody, not even your doctor. This will ascertain that the valuable medical data for science and research will be preserved.

We are very pleased about your participation in the DHR, and would deeply appreciate your full trust in us!
The original remains with the treating doctor. The patient receives a copy.

My treating doctor has informed me about the DHR (*Deutsches Hämophilieregister*, German Haemophilia Registry).

I agree to my personal data in the DHR being processed as set forth in detail in the written patient information. With this informed consent, I also release my treating doctor, as indicated above, from his secrecy obligation to the extent that this is required for the participation in the DHR.

I have been informed that my participation in the DHR is voluntary, and that I have the right to withdraw my consent at any time without stating any reasons. A rejection of my participation will not involve any disadvantage for me. In the event of me withdrawing my consent, the data stored in the DHR up to that moment will be anonymised and assigned to a random code number. No further data about me will be recorded.

I have received the written patient information about the DHR. I have been informed on the personal and health data to be communicated to the DHR, operated at the PEI. Furthermore, I have been informed that my pseudonymised data can be recorded, processed and used both by the parties contributing to the DHR, and in the field of science and research.

I was given the opportunity to ask questions. These were answered to my satisfaction and in their completeness. The scope and course of my participation in the DHR have been made transparent to me. The following questions were discussed in addition to the written information provided:

I understand that the data communicated to the DHR is personal data of special nature as laid down in Section 3, subsection 9 *BDSG* (*Bundesdatenschutzgesetz*, Federal Data Protection Act), i.e. that the data transmitted concerns my state of health.
Informed Consent

The original remains with the treating doctor. The patient receives a copy.

First and last name of the patient
Address

My treating doctor has informed me about the DHR (*Deutsches Hämophiliregister, German Haemophilia Registry*).

Title, last name, first name of the doctor
Address of doctor’s practice/medical centre (stamp)

I agree to my personal data in the DHR being processed as set forth in detail in the written patient information. With this informed consent, I also release my treating doctor, as indicated above, from his secrecy obligation to the extent that this is required for the participation in the DHR.

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City or town, date Patient’s signature

City of town, date Doctor’s signature

Version 1.1