InfCareHepatit

Patient information regarding InfCareHepatit – a National Quality Register and a Decision support system

InfCareHepatit is a National Quality Registry for Hepatitis B, C and D. The main purpose of the registry is to develop the quality of care. Data is collected by healthcare professionals and from patients.

What is registered is information that concerns the care and treatment of your hepatitis and its complications. The information that is registered is: personal identification number, virus type (Hepatitis B, C and D), virus amounts, liver values, results from liver elasticity measurement, what treatments you are receiving and have received and any complications of the hepatitis infection (liver cirrhosis and liver cancer).

The entity with overall responsibility is called the Central Data Protection Authority, CPUA. Karolinska University Hospital has overall legal responsibility for the personal data in InfCareHepatit – quality register and decision support.

The clinic you visit for care has local legal responsibility for data collection.

Below you will find more information about quality registers and decision support in InfCareHepatit.

The decision support in InfCareHepatit

The decision support is a registered medical device and is counted as part of the medical record. This means that the same laws and regulations that apply to the medical record also apply to the decision support. The decision support gives your doctor/nurse a quick overview of virus samples, which treatments you have received and the effect of these treatments. The decision support can also be used during clinical visits when you and your doctor/nurse can look at your values and discuss the results.

The Quality Register in InfCareHepatit

You contribute to better care

Participating in a quality register is voluntary and does not affect the care you receive. By being part of a National Quality Register, you contribute to better care. The data is used to compare care between different hospitals and care providers around the country. The results can be used for improvement work and research. The quality registers contribute to new knowledge about the best treatment and care for patients with Hepatitis B,C and D, and the more patients that are included, the safer the

results. The knowledge we gain is then used in our daily work to improve hepatitis care for you and for others with viral hepatitis.

Contact information

More information is available at www.infcarehepatit.se

When information about you is included in a quality register, you have certain rights. Read more about them below. If you would like to contact InfCareHepatit – quality register and decision support regarding your rights, please use these contact details:

Magdalena Ydreborg, registry holder

Telephone: 031-342 10 00

E-mail adress: magdalena.ydreborg@vgregion.se

You can also contact a Data protection officer with questions regarding your data in quality registers. Data protection officers monitor compliance with laws regarding the processing of personal data.

Contact information for the Data protection officer at Karolinska University Hospital:

Dataskyddsombudet, Karolinska Universitetssjukhuset, 17176 Stockholm

Telephone number: 08-51770000

E-mail adress: dataskyddsombud.karolinska@regionstockholm.se

InfCareHepatit

Laws and regulations

Anyone who processes personal data must rely on a legal basis. The handling of personal data in quality registers is regulated by the data protection regulation, GDPR, and chapter seven of the Patient Data Act, PDL. It is permitted to register data in quality registers because the data is of general interest to society and important in healthcare. The personnel who handle personal data in quality registers are subject to a statutory duty of confidentiality.

How your data is used

Information is recorded in the quality register in order to enable the quality of thecare provided to be continually improved and to provide statistical information. The data may also be used in research but only with the approval of the Ethical Review Authority. Data may furthermore be subject to data discovery for clinical research.

When statistical information from the registers is published it is impossible to identify information relating to any particular individual.

These persons have access to information about you

Authorized personnel at the healthcare facility that has entered the data into the quality register have access to this data only. No other healthcare provider has access to the data. Authorized personnel or the responsible CPUA authority working on the quality register have access to all data in the register.

This is how your data are protected

The information about you as a patient is protected by several laws: EU's General DataProtection Regulation, the Public Access to Information and Secrecy Act and thePatient Data Act. This means that there are strict regulations concerning who can have access to the information about you. The information has the same strong protection as your medical case notes. There are also controls to ensure that no unauthorized person can gain access to the information, that your data are protected by encryption and that access to the data can only be achieved by logging in according to a secure procedure.

Legal support for the Swedish National Quality Registries

All persons processing personal data must be legally authorised in accordance withEU's General Data Protection Regulation, and also in certain cases also by Swedish or other legislation. The Swedish National Quality Registers are considered to carry

out a task in the public interest in accordance with Article 6 e of EU's General DataProtection Regulation and are therefore permitted.

The Quality Registers are also regulated by Chapter 7 of the Patient Data Act.

There is thus legal support for us and for the region responsible for the National Quality Register processing your data. Information about a person's health is classifiedas sensitive personal information and the processing of such information requires a legal basis, but such data may according to the EU's General Data Protection Regulation be recorded in the register because it is necessary for reasons related to the medical profession and the provision of health and sickness care (Article 9.2h) and it is also supported by the Patient Data Act.

Storage time and removal of data

Information relating to you will be removed when it is no longer needed for developing and ensuring the quality of health care. The archive authority in the region responsible for the National Quality Register may however decide to save your information until further notice for use for historical, statistical or scientific purposes.

Your rights

At this health centre, we register information in the National Quality Register. If you as a patient do not wish us to register information about you, you have the right to choose not to participate. If so, please inform the staff or contact the keeper of the register afterwards. See the information above.

You also have other rights:

- You have at any time the right to ask that the information about you be removed from the register.

- You have the right to receive confirmation that personal data relating to you are being processed in the region responsible for the quality register and if so to receive a copy of your personal data free of charge.
- You have the right to know to what categories of recipient your information may be given, e.g. for research purposes.
- You also have the right to know whether information about you is taken from any other source than your medical case notes or you personally.
- You have the right to receive your personal data in an electronic format.
- You have the right to have incorrect personal data corrected and to complement incomplete personal data.
- Under certain conditions, you have the right to request that the processing of your data be restricted. This applies during the time when other rights claimed by you are being assessed. The restriction means that the National
- Quality Registries can do nothing with your data other than to continue storing them.
- You have the right to information regarding which care unit and at what time someone has had access to your data. You have the right to damages if your

personal data are handled in conflict with EU's General Data Protection Regulation or the Data Protection Act.

- You have the right to submit a complaint to the Swedish Data Protection Authority.

You can read more about all the National Quality Registries at
www.kvalitetsregister.se