The European HBV Registry - A joint initiative of TherVacB and DZIF

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Data source **Human** **Disease registry**

Administrative details

Administrative details

Data source ID

49034

Data source acronym

HBV Registry

Data holder

Hannover Medical School (MHH)

Data source type

Disease registry

Main financial support

European public funding

National, regional, or municipal public funding

Care setting

Hospital inpatient care

Hospital outpatient care

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

No

Data source website

https://www.thervacb.eu/de/patienten/das-europaeische-hbv-patientenregister/

Contact details

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Data source regions and languages

Data source countries

Germany

Italy

Spain

Data source languages

English

Data source regions

Barcelona [Barcelona]

Bayern

Hamburg

Niedersachsen

Parma

Sachsen

Data source establishment

Data source established

06/05/2021

Data source time span

First collection: 06/05/2021

The date when data started to be collected or extracted.

Publications

Data source publications

Registry entry on clinicaltrials.gov

Studies

List of studies that have been conducted using the data source

The European HBV Registry: A joint initiative of TherVacB and DZIF (HBV Registry)

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

Disease details (other)

HBV- and HDV Virology (qualitative + quantitative), Blood biochemistry, Hematology, Liver disease, Antiviral therapy

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Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

No

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

Other

Cause of death vocabulary, other

"cause of death HBV related" (yes/no)

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

Active ingredient(s) listed

Dispensing of medicines

Not Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Not Captured

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Not Captured

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Captured

Genetic data vocabulary

Other

Genetic data vocabulary, other

HLA genotype

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

Quality and quantity of virological measures (HBsAg, HBeAg, Anti-HBe, Anti HDV, HBV-DNA, HBV-RNA)

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

Yes

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

No

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

Other

Diagnosis / medical event vocabulary, other

Virological measures, concomitant conditions (e.g. NASH, AIH, malignancies etc.), LFU, death

Medicinal product information

Not Captured

Quality of life measurements

Captured

Quality of life measurements vocabulary

EQ5D

other

Quality of life measurements, other

EQ-5D-5L recommended, but not mandatory

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Ethnicity

Gender

Quantitative descriptors

Population Qualitative Data

Population age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

Not available

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are

registered only for private care)

Not collected: patients with unknown infection, patients treated elsewhere.

Population

Population size

230

Active population size

224

Population by age group

Age group	Population size	Active population size
Adults (18 to < 46 years)	87	84
Adults (46 to < 65 years)	112	110
Elderly (≥ 65 years)	31	30
Adults (65 to < 75 years)	26	25
Adults (75 to < 85 years)	5	5
Adults (85 years and over)	0	0

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

0.90

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

0.90

Data flows and management

Access and validation

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

Yes

Biospecimen access conditions

Steering Committee

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

Description of data collection

Patient data is gathered from the respective hospital documentation (patient files) and entered into the registry

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

Patient with HBV diagnosis agrees to participate in registry by signing informed consent at one of their (routine) visit to the outpatient department

Event triggering de-registration of a person in the data source

Death

Loss to follow up

Practice deregistration

Event triggering creation of a record in the data source

Routine visit to outpatient department

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

No

Data management specifications that apply for the data source

Informed consent for use of data for research

Other

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

Yes

Data source preservation

Are records preserved in the data source indefinitely?

No

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

Informed consent, other

There is a steering committee to evaluate requests for data access

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No