The Bulgarian Diabetes Register and the Register of rare endocrine deseases

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Data source | Human | Hospital discharge records | Primary care medical records | Specialist ambulatory care records

Administrative details

Administrative details

Data source ID

1111123

Data source acronym

BDR-RRED

Data holder

Technical University of Sofia

Data source type

Hospital discharge records

Primary care medical records

Specialist ambulatory care records

Main financial support

European public funding

National, regional, or municipal public funding

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – GP, community pharmacist level

Primary care – specialist level (e.g. paediatricians)

Secondary care – specialist level (ambulatory)

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.

Yes

Description of the qualification

The Bulgarian Diabetes register is established following the orders of the Minister of Health № РД-09-167/01.10.2013 г. and № РД-02-26/24.01.2015 г.The Register of Rare endicrine deseases is created and maintained in accordance with the requirements of Ordinance No. 16 of the Ministry of Health from July 30, 2014 on the terms and conditions for registering rare diseases and for expert
centers for rare desease and reference networks for rare diseases - The USHATE is an expert center for rare endocrine diseases and participetes in the European network for rare endocrine deseases - EndoERN.

Data source website

https://usbale.org/bg/

Contact details

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Data source regions and languages

Data source countries

Bulgaria

Data source languages

Bulgarian

English

Data source establishment

Data source established

15/06/2008

Data source time span

First collection: 01/01/1980

The date when data started to be collected or extracted.

Publications

Data source publications

Чаръкчиев Д., С. Захариева, Г. Ангелова, Св. Бойчева, Ж. Ангелов, П. Маринова, Г. Ненчовска, Л. Манева, А. Величков, Г. Петрова, К. Копривaрова, И. Стоева, М. Боянов, Р. Савова, Р. Радев, Л. Стойкова-

Чорбанова, Е. Ташева, П. Денчева, Е. Фотева, К. Славчева, Б. Стоянов, А. Стоев, С. Алексиева, Е. Котова, И. Ковачева, Т. Томов. Изграждане на български националнен регистър на болните от захарен диабет Соц. Мед. 2015, № 2 19-21. ISSN 1310-1757 (Building a Bulgarian national registry of patients with diabetes mellitus)

Чаръкчиев Д., Х. Димитров, С. Захариева, М. Маринов, С. Вындева, В. Василев, М. Янева, А. Еленкова, Е. Начев, Г. Кирилов, И. Атанасова, Р. Иванова. База данни за пациенти с хипофизни и надбъбречни тумори. Соц. мед. 2010, № 2-3, 73-79. ISSN 1310-1757 (Data base for patients with pituutary and adrenal tumors)

Vandeva S., A. Elenkova1, E. Natchev1, G. Kirilov1, D. Tcharaktchiev, M. Yaneva1, K. Kalinov, M. Marinov, K. Hristozov, Z. Kamenov, M. Orbetzova, J. Gerenova, I. Tsinlikov, S. Zacharieva. Treatment Outcome Results from the Bulgarian Acromegaly Database: Adjuvant Dopamine Agonist Therapy is Efficient in Less than One Fifth of Non-irradiated Patients. Exp Clin Endocrinol Diabetes 2015; № 123, p. 66–71. ISSN 0947-7349

Krastev E, Tcharaktchiev D, Markov E. System of Criteria for Treatment Evaluation of Acromegaly in Bulgaria. Studies in Health Technology and Informatics, 2020, 272, pp. 413–416 (18th International Conference on Informatics, Management and Technology in Healthcare 2020, Greece 3-5 July https://www.icimth.com/), (open access, Scopus, Web of Science) https://ebooks.iospress.nl/publication/54683

Krastev E, Tcharaktchiev D, Kovachev P, Abanos S. Diabetes and Obesity in Bulgaria. Study of a Large Number of Outpatient Records from 2018. Advances in Informatics, Management and Technology in Healthcare, J. Mantas et al. (Eds.) ICIMTH 2022: 298-301. doi: 10.3233/SHTI220721. PMID: 3577386

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)

The Bulgarian Diabetes Register includes more than 503 000 active patients - ICD-10 codes: E10 - E14; and the Register of rare endocrine deseases includes more than 5700 cases with ICD - 10 codes: C74.0;C75.1;C75.2;C75.3;C75.4;C75.5;C75.8;D35.5;D35.6;D44.5;D44.6;D44.7;D44.8; E22.0 (1062 patents wiith acromegaly); E22.1;E22.2;E22.8;E23.0;Q87.1;E23.2;E24.0;E24.1;E24.3;E24.8;E25.0;E25.8;E25.9;E26.0;

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.

Yes

Pregnancy and/or neonates

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

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

ICD-10

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

other

Prescriptions vocabulary, other

National Health Insurance Fund codes of medicinal products

Dispensing of medicines

Captured

Dispensing vocabulary

other

Dispensing vocabulary, other

National Health Insurance Fund codes of medicinal products

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)].

Yes

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?

Captured

Indication vocabulary

ICD-10

Medical devices

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

Yes

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

ICD-9-CM

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.

Yes

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?

Not Captured

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

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

ICD-10

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Dose

Strength

Medicinal product vocabulary

ATC

Other

If 'other,' what vocabulary is used?

National Health Insurance Fund codes of medicinal products

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Diet

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Gender

Health area

Marital status

Socioeconomic status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

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

95%. The Bulgarian Diabetes register pratically includes all established diabetics in the country, The Register of rare endocrine desease includes about 95% of diagnosed in the country patients with rare endocrine deseases

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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)

All Bulgarian population and foreign residents

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Ad hoc

Population

Population size

608310

Active population size

505562

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	2385	2350
Adults (18 to < 46 years)	34962	28901
Adults (46 to < 65 years)	215466	178700
Elderly (≥ 65 years)	355497	295611

Median observation time

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

21.00

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

15.00

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

https://usbale.org/bg/registar-zaharen-diabet/

Biospecimen access

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

No

Access to subject details

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

Yes

Description of data collection

Both the Bulgarian Diabetes Register and the Register of Rare Disease are used for collecting and recording of data.

Data holder: Technical University of Sofia and University Specialised Hospital for Active Treatment of Endicrinilogy (USHATE)

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

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

Death

Loss to follow up

Event triggering creation of a record in the data source

Hospital Discharge, Patient visit, GP encounter, Specislis encounter

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?

Yes

Linkage description, possible linkage

The data from the Bulgarian National Cancer Registry can be linked to the data from the Bulgarian Diabetes Register and the Register of Rare Endocrine Deseases

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Bulgarian National Cancer Registry, others possible data sources to be linked to depend on expressed interest

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Linkage strategy

Deterministic

Linkage variable

Anonymised Patient Identificator

Linkage completeness

In the process of planning of the major activities

Data management specifications that apply for the data source

Data source refresh

Quarterly

Informed consent for use of data for research

Not Required

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?

Yes

Approval for publication

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

Yes

Data source last refresh

31/03/2023

Common Data Model (CDM) mapping

CDM mapping

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

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data source ETL CDM version

5.3

Data source ETL status

In progress