

BELpREG: the Belgian pregnancy registry

First published: 01/02/2024

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Data source

Human

Other

Administrative details

Administrative details

Data source ID

1111212

Data source acronym

BELpREG

Data holder

[KU Leuven](#)

Data source type

Other

Data source type, other

Prospective pregnancy registry, not medicine or disease specific

Main financial support

Funding by own institution

Care setting

Hospital outpatient care

Primary care – GP, community pharmacist level

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.

No

Data source website

<https://www.belpreg.be>

Contact details

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Main

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Data source regions and languages

Data source countries

Belgium

Data source languages

Dutch

English

French

Data source establishment

Data source established

01/11/2022

Data source time span

First collection: 06/11/2022

The date when data started to be collected or extracted.

Publications

Data source publications

Development and design of the BELpREG registration system for the collection of real-world data on medication use in pregnancy and mother-infant outcomes

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

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

Not coded (Free text)

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

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?

Yes

Indication for use

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

Captured

Indication vocabulary

ICD

MedDRA

Medical devices

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

No

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

Not coded (Free text)

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?

No

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.

Not Captured

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?

Yes

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

MedDRA

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

ATC

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Other

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Ethnicity

Marital status

Other

Socioeconomic status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

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

the registry was established in november 2022. Currently, we have enrolled about 400 pregnant women, but the registry is growing every day as more healthcare professionals in Belgium are becoming aware of BELpREG and motivate their pregnant patients to participate. Overall, 60 000 pregnant women per year in Flanders, Belgium (i.e., Dutch speaking part of Belgium).

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)

enrolment in BELpREG by pregnant women is voluntary.

Family linkage

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

Permanently

Family linkage available between the following persons

Mother-child

Population

Population size

400

Active population size

400

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	100	100
Adults (18 to < 46 years)	400	400

Median observation time

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

31.00

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

31.00

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://doi.org/10.3389/fdsfr.2023.1166963>

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

digital questionnaires as part of a REDCap project

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

Being currently pregnant

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

Other

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

Miscarriage, elective abortion, ectopic pregnancy or stillbirth

Event triggering creation of a record in the data source

pregnant women enroll themselves by completing the digital informed consent through the BELpREG website (see www.belpreg.be)

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

Linkage description, possible linkage

Not yet, but opportunities with linkage to other databases in Belgium are being explored (e.g., with respect to infant development, health administrative data, ..). In the future, data pooling with BELpREG data may also occur with other institutes belonging to the European Network of Teratology Information Services (ENTIS) who also collect medication exposure in pregnancy data and outcomes.

Data management specifications that apply for the data source

Data source refresh

Monthly

Informed consent for use of data for research

Required for all studies

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?

No

Data source last refresh

06/10/2023

Common Data Model (CDM) mapping

CDM mapping

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

No