

# Validity of using prescription records to identify patient comorbidities

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000359

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### Study ID

1000000359

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

The aim of this study is to assess the validity of using prescription records for identifying several patient comorbidities in routinely collected electronic health records and to identify predictors for misclassification. The study design is a

retrospective data linkage study, following the design of an evaluation of medical tests for classification and prediction.

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## Study status

Planned

## Research institutions and networks

### Institutions

#### Queen's University Belfast

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Institution

Educational Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Liam Heaney 0000-0002-9176-5564

Primary lead investigator

**ORCID number:**

0000-0002-9176-5564

## Study timelines

### **Date when funding contract was signed**

Actual: 23/05/2023

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### **Study start date**

Planned: 01/11/2024

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### **Data analysis start date**

Planned: 01/11/2024

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### **Date of final study report**

Planned: 01/05/2025

## Sources of funding

- Non-EU institutional research programme

## More details on funding

Health Data Research UK (HDR-UK, <https://www.hdruk.ac.uk/>)

## Study protocol

[schnier et al Validation.pdf](#) (167.79 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Other

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**Study topic, other:**

Validation study in electronic health data research

**Study type:**

Non-interventional study

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**Scope of the study:**

Validation of study variables (exposure outcome covariate)

**Data collection methods:**

Secondary use of data

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**Study design:**

The study design is a retrospective data linkage study, following the design of an evaluation of medical tests for classification and prediction.

**Main study objective:**

The primary aim of this study is to assess the validity of using prescription records for identifying patient comorbidities. We additionally identify predictors for misclassification.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name, other**

Several combinations of drugs indicative of a comorbidity

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**Additional medical condition(s)**

Several comorbidities that are common, non-communicable, are pharmacological treated and where medications are reasonably specific to treating the condition.

## Population studied

**Short description of the study population**

Adult patients of UK GP practices who, between 2004 and 2024, have been registered with a GP practice that contributes to Optimum Patient Care

## Age groups

- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to  $< 65$  years)
    - Adults (18 to  $< 46$  years)
    - Adults (46 to  $< 65$  years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to  $< 75$  years)
    - Adults (75 to  $< 85$  years)
    - Adults (85 years and over)

## Study design details

### Setting

A random subset of the study population is drawn from the OPCRD database. For each patient in the subset, a random index date is created between 2004 and 2024 that allows a 3-year follow-up (follow-up period). For the follow-up period, all medical records are interrogated for a diagnosis indicative of a specific disease (gold standard). For the same period, all prescription records are interrogated for a prescription record indicative of the same disease (index test).

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### Outcomes

Sensitivity, Specificity, Predictive Values and Likelihood Ratios will be calculated for each disease. To identify predictors for misclassification, test accuracy is calculated for different strata of the study population.

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### Data analysis plan

The probability of misclassification (positive predictive value and negative predictive value) conditional on potential predictors (covariates) is calculated using multilevel logistic regression models. Observations from patients of the same GP practice are most likely correlated, therefore the practice identifier will be included in any model as random effect.

In sensitivity analysis, we will potentially include (a) a shorter study period (1 year); (b) compare alternative code lists (e.g., only include codes that are indicative of a severe case); (c) analyze time-to-prescription in a survival analysis; (d) modify the definition of a test positive record (e.g., 2 or more prescriptions).

Data management and analysis will be conducted using Microsoft SQL Server and Stata (V18), respectively.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s)**

Optimum Patient Care Research Database

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### **Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No