Quantitative bias analysis for outcome phenotype error correction in comparative effect estimation: an empirical evaluation and simulation study (QBA evaluation)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105663

EU PAS number

EUPAS104459

Study ID

105663

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Outcome phenotype error is acknowledged but rarely corrected for in causal effect estimation studies using observational data. Quantitative bias analysis (QBA) is a method for phenotype error correction, but the extent to which it minimizes bias in effect estimates is unclear. We will empirically evaluate the impact of QBA for outcome phenotype error correction in several pharmacoepidemiologic comparative effect estimation scenarios. Further, we will simulate an analytic space defined by outcome incidence, observed effect estimates, and phenotype measurement errors to determine which QBA input combinations produce valid results.

Study status

Ongoing

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

James Weaver

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/06/2021

Actual: 10/06/2021

Study start date

Planned: 03/01/2022

Actual: 03/01/2022

Date of final study report

Planned: 29/12/2023

Sources of funding

- Other

More details on funding

Clarendon Fund, University of Oxford

Study protocol

EUPAS104459_protocol.pdf(542 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Observational research methods

Main study objective:

1) Empirically evaluate QBA for outcome phenotype error correction in several pharmacoepidemiologic comparative effect estimation scenarios 2) Simulate an analytic space defined by outcome incidence, observed effect estimates, and phenotype measurement errors to determine which QBA input combinations produce valid results

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

6000000

Study design details

Data analysis plan

Quantitative bias analysis (QBA) provides algebraic adjustment of person counts in an exposure by outcome 2x2 contingency table based on the magnitude of outcome misclassification. We will evaluate the impact of QBA for outcome phenotype error correction in several empirical and simulated comparative effect estimation pharmacoepidemiologic scenarios. We will evaluate QBA performance with several bias correction metrics.

Data management

Data sources

Data source(s), other

Optum Electronic Health Record United States, Optum Extended Clinformatics United States, IBM Commercial Database United States, IBM Medicaid State-Sponsored Beneficiaries United States, IBM Medicare Supplemental Beneficiaries United States

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Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No