Reproducible Evidence: Practices to Enhance and Achieve Transparency (REPEAT)

First published: 29/06/2017

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Study Planned

Administrative details

EU PAS number

EUPAS19636

Study ID

50407

DARWIN EU® study

No

Study countries

☐ United States

Study description

Large healthcare database research informs both clinical and payment decisions as well as improves the quality and affordability of healthcare for public health. Interest and capacity to use data contained in large healthcare databases has increased exponentially, however, much of the evidence from those valuable large healthcare databases suffers from lack of reproducibility, transparency and scientific robustness. This project aims to evaluate the current state of reproducibility of large published healthcare database studies. We will achieve this objective by taking a systematic random sample of healthcare database studies published in a leading clinical or epidemiology journal within the last 5 years and attempting to reproduce them based on the reported methods in publications and appendices. We plan to sample studies that were conducted using different large healthcare data sources.

Study status

Planned

Contact details

Study institution contact

Shirley Wang swang1@bwh.harvard.edu

Study contact

swang1@bwh.harvard.edu

Primary lead investigator

Shirley Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/08/2017

Study start date
Planned: 01/08/2017

Data analysis start date
Planned: 01/08/2018

Date of final study report
Planned: 01/01/2021

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Other

More details on funding

Laura and John Arnold Foundation, Brigham and Women's Hospital

Study protocol

PROTOCOL 2017-06-06.pdf (460.97 KB)

Amendment Jan 2022.pdf (73.84 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:

Other

Drug utilisation

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

Methodological

Main study objective:

Our objective is to measure the current state of reproducibility for database research and empirically validate specific guidance/recommendations on what to report in order to achieve consistently reproducible and robust findings from healthcare database studies.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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)

Special population of interest

Renal impaired

Hepatic impaired

Pregnant women

Estimated number of subjects

250

Study design details

Outcomes

The primary outcomes for each replicated study will be the primary outcomes reported in the original paper.

Data analysis plan

•Descriptive frequencies for insufficient reporting on specific parameters•Standardized differences for baseline characteristics, incidence rates, and reported measures of association in original and replication•Calibration of measures of association in the original and replication•Relationship between lack of transparency in different areas (e.g. timing of cohort entry and follow up, algorithms to measure exposure, outcome, covariates etc.) and standardized differences in the original versus replication.•Proportion of studies with clear design or analysis flaws stratified by type. These may include immortal time bias, reverse causation, adjustment for intermediates,etc.•Plot measures of association with 95% CI for the original paper,replications using original methods, using plausible alternative choices, after external adjustment for residual confounding,after quantitative and probabilistic bias correction, after correction of clear design flaws,and using negative controls

Documents

Study publications

Wang, S.V., Sreedhara, S.K., Schneeweiss, S. et al. Reproducibility of real-wor…

Wang SV, Sreedhara SK, Bessette LG, Schneeweiss S. Understanding variation in t…

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.

Conflicts of interest of investigators

conflict of interest.pdf (171.8 KB)

Composition of steering group and observers

Steering Board.pdf (84.08 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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