Big Data for Medical Devices: European multi-national research leveraging routinely collected (medical records, registries) health data

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Background

- Devices are seldom compared in randomized controlled trials.
- New EU legislation will require comprehensive observational post-marketing surveillance.
- Yet, data, tools, and methods for such research are lacking.

- Our aims are therefore:
  1. *To develop and test a platform for EU-wide observational device safety research;*
  2. *To develop and validate statistical methods to minimise bias in observational device research*

Methods

Data sources: multi-national European electronic medical records (EMR) and -where possible- linked orthopaedic device registries will be mapped to the OMOP common data model.

Exposures: different types of knee/hip replacement prostheses as identified in linked orthopaedic registries will be compared

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Methods (2)

Outcome/s:
1.Adverse device reactions (ADRs), including post-operative infection, venous thrombo-embolism and surgical complications and mortality will be identified in the mapped EMRs,
and *2.Patient reported outcomes* from linked orthopaedic registries

Analytical Methods: Potential ADRs will be identified using data driven safety signal detection algorithms in mapped datasets. Impact (incidence and morbi-mortality) and their association with device type will be estimated in a federated analysis of mapped data.
Strategies popular in drug safety research will be combined with multi-level modelling to account for surgeon/centre variables. These will be validated in simulation studies and shared with the OHDSI community.

Expected Results / Impact

We will develop and validate a European platform and validate analytical strategies for observational device comparative safety research, hence providing a framework for EU medical device post-marketing surveillance.