Effect of bariatric surgery on cancer risk: identifying appropriate non-exposed controls for a cohort study

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BACKGROUND

- Real World Data (RWD) promises to vastly expand clinical research.
- However, observational studies can yield **biased results** when improperly designed.
- **Target trial emulation** using RWD can help overcome this limitation.

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BACKGROUND

- RWD can be used to address whether the risk of specific cancer types is **reduced** after Bariatric Surgery (BS).
- Previous studies addressing this question have mostly found **non-significant** or inconsistent results.

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BACKGROUND

- OHDSI offers a unique opportunity to study BS and cancer risk as it includes over 1.5 billion individual records from 20 countries with highly detailed information on patients.

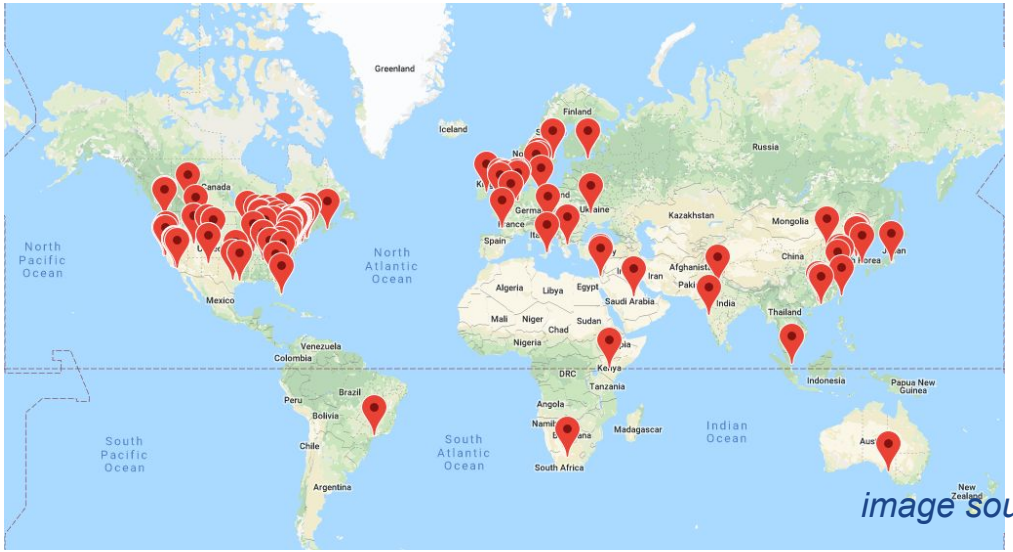

image source: ohdsi.org

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BACKGROUND

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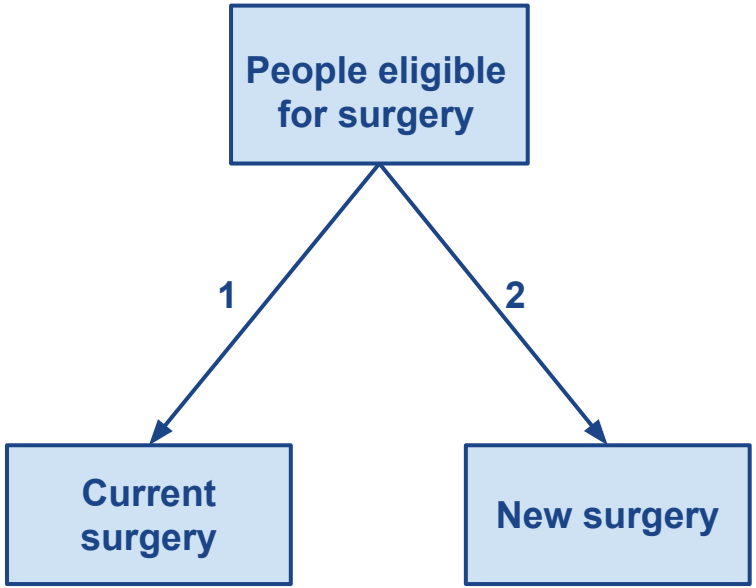
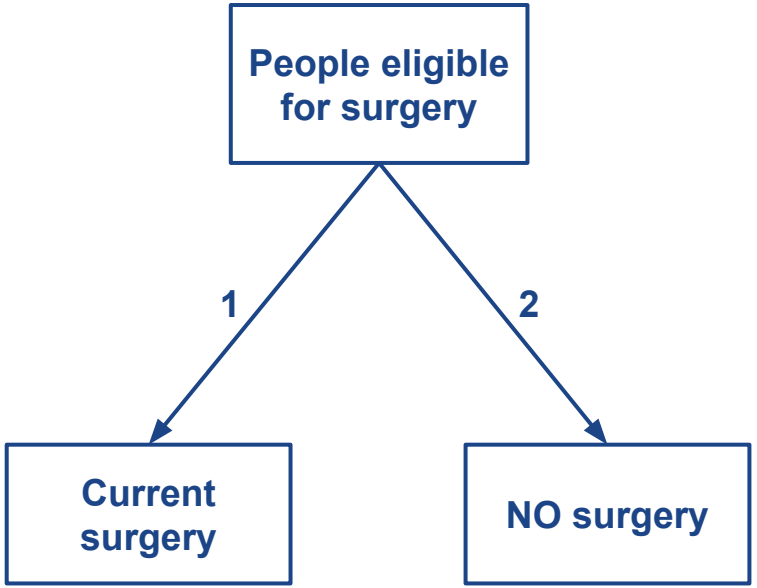


Clear exposure

OHDSI tools



Index date for group 2?

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OBJECTIVES

- Our aim is to briefly describe a **protocol** to study specific-site cancer risk after bariatric surgery in the OHDSI network and address the issue of identifying appropriate **non-exposed controls**.

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STUDY METHODOLOGY

- Matched cohort study.
- Databases mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM).
- Study start dates vary according to each database (earliest 01/01/2000 - latest 31/12/2019).

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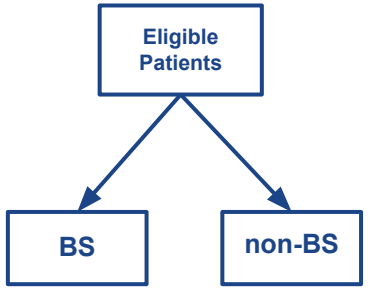
STUDY METHODOLOGY



- We will build two mutually exclusive cohorts.
- Inclusion criteria:
  - Aged ≥18 years
  - With a record of body mass index (BMI)≥35 kg/m2 or an obesity diagnosis
  - without history of BS nor cancer
  - have been on the database for 1 year before study entry
  - have at least 1 year of follow-up

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STUDY METHODOLOGY

- **Main exposure:** BS
- **Main outcome:** Incident diagnoses of obesity-related cancers.
- **Covariates:** Sociodemographics, diagnoses, procedures, measurements and devices.

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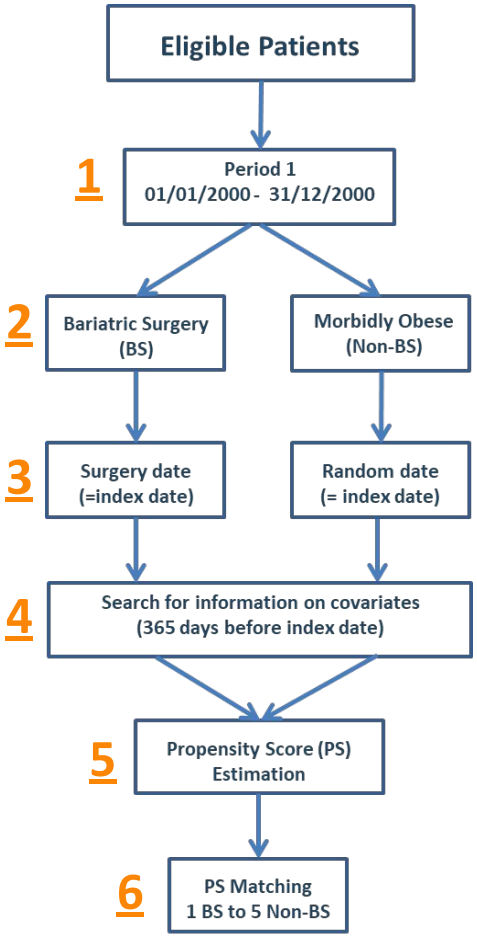
A MATCHING PROCESS TO EMULATE A TARGET TRIAL



1: We split the study period in 1-year windows.

2: We assign patients into the BS and non-BS cohorts.

3: **BS cohort: index date = surgery date.**
Non-BS cohort: index date = random date.

4: We identify the covariates from 1 year prior to their index date.

5: We estimate propensity scores (PS).

6: We match 1 BS patient with up to 5 non-BS patients.

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STATISTICAL ANALYSES

- We fit Cox proportional hazard models to estimate the risk of developing each cancer.
- We will check for residual confounding using negative outcomes.

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FINAL REMARKS

- It is possible to emulate a target trial even without a clearly defined index date for non-exposed controls.
- Analogous to in a target trial, patients in the non-BS cohort at period X, could still undergo a BS in the future.
- A network study will soon be proposed to the OHDSI Community using this protocol.

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