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A strawman for harmonization of a obesity observational study

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What problem are we solving?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, drug use, etc.) between patients taking one or more weight loss medications vs. patients s/p bariatric surgery?

What data do we need?

Estimation of 12-month risk of **cardiovascular event**, adjusting for baseline risk factors (**diabetes, hypertension**, drug use, etc.) between patients taking one or more weight loss medications vs. patients s/p bariatric surgery?

- Condition occurrence
  - Need information for outcome and covariates
  - Assuming conditions will come from diagnosis codes in inpatient/outpatient medical claims + EHR problem lists + patient self-report, etc.
  - Assuming conditions will be coded in different source values (e.g. ICD-9-CM, ICD-10, SNOMED, freetext…)

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What data do we need?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, **drug use**, etc.) between patients taking **one or more weight loss medications** vs. patients s/p bariatric surgery?

- Drug exposure
  - Need information for exposed cohort and covariates
  - Hope required information is prescription medications, otherwise risk that many systems won't capture OTC
  - Assuming drugs will come from pharmacy dispensing + physician order entry + EHR medication history + patient self-report, etc.
  - Assuming drugs will be coded in different source values (e.g. NDC, GPI, Multum, VAProduct, freetext…)
  - Need standardized approach to infer length of exposure

What data do we need?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, drug use, etc.) between patients taking one or more weight loss medications vs. patients **s/p bariatric surgery**?

- Procedure occurrence
  - Need information for exposed cohort and covariates
  - Assuming drugs will come from inpatient/outpatient medical claims + physician order entry + patient self-report, etc.
  - Assuming procedures will be coded in different source values (e.g. CPT-4, ICD-P, freetext…)

What data do we need?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, drug use, etc.) between patients taking one or more weight loss medications vs. patients s/p bariatric surgery?

- Observation
  - Need other types of clinical observations, such as vitals (Height, Weight, BMI) and lab tests (hbA1C), for cohort criteria and covariates
  - Assuming observations will come from EHRs and lab services + patient self-report, etc.
  - Assuming observationss will be coded in different source values (e.g. LOINC, freetext…)

What data do we need?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, drug use, etc.) between patients taking one or more weight loss medications vs. patients **s/p bariatric surgery**?

- Provider
  - Need information for covariate adjustment
  - Assume provider specialty captured with different source values (CMS, etc.)
  - Need provider identifier linked to each procedure infer level of experience

What data do we need?

Estimation of 12-month risk of cardiovascular event, adjusting for baseline risk factors (diabetes, hypertension, drug use, etc.) between patients taking one or more weight loss medications vs. patients s/p bariatric surgery?

- Observation period
  - Need information for cohort definition
  - Need to infer when a person is in the healthsystem and should be expected to be observable for health services
  - Payer systems: enrollment
  - EHR: inference/assumptions often needed, may need standardization across network?

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Next step: Review alternative existing data models

Data Model Considerations for Clinical Effectiveness Researchers

Michael G. Kahn, MD, PhD,†‡ Deborah Batson, BS,‡ and Lisa M. Schilling, MD, MSPH§*

(*Med Care* 2012;50: S60–S67)

CLINICAL INFORMATICS

(*Med Care* 2013;51: S45–S52)

Identifying Appropriate Reference Data Models for Comparative Effectiveness Research (CER) Studies Based on Data from Clinical Information Systems

Omolola I. Ogunyemi, PhD, Daniella Meeker, PhD,† Hyeon-Eui Kim, RN, MPH, PhD,‡ Naveen Ashish, PhD,§ Seena Farzaneh, BSc,‖ and Aziz Boxwala, MD, PhD‡*

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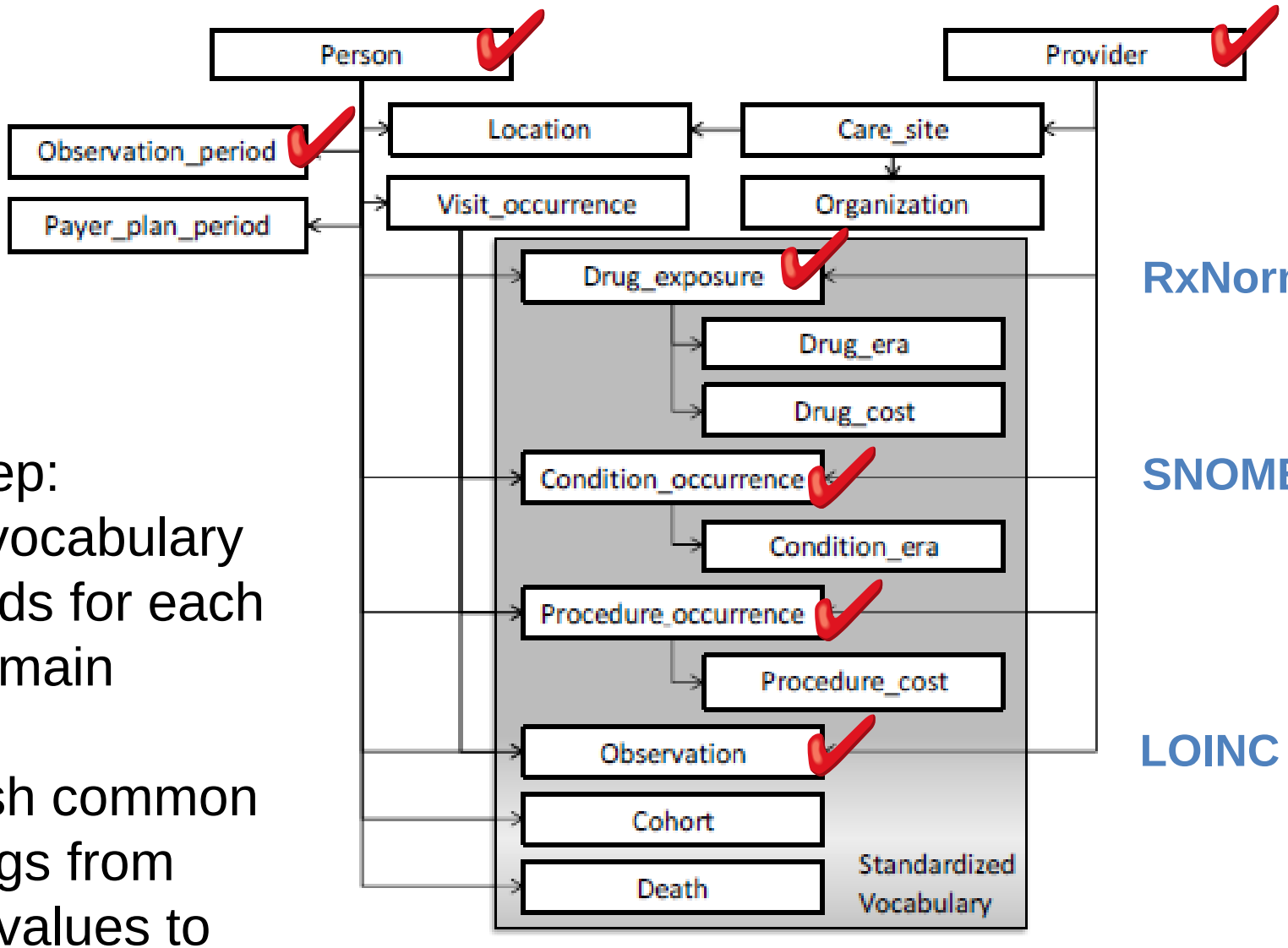
Find model that supports data needs: example approach: OMOP CDM



Next step:
Select vocabulary standards for each data domain

Establish common mappings from source values to each standard

http://omop.org/CDM

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Now that we've standardized structure and content

- Needs for harmonizing analysis process
  - Feasibility assessment - patient counts of exposed groups
  - Data quality assessment
  - Multivariate modeling
    - Program tested against model and disseminated to all partners
    - Assuming sites may be on different database systems (Oracle, SQL, SAS) and different operating systems
    - Program could be DE NOVO or ESTABLISHED MACRO (modular program) , and could be developed in different in different languages (SAS, R, SQL, C++, Java)
- Execute suite of analysis programs not just for the question of interest, but also for positive/negative controls to calibrate interpretation and establish operating characteristics

- Standardized output
  - Full transparency, all summary results (but not patient-level data) shared across all sites and all participating researchers
  - Collective interpretation of site-specific results and well as overall conclusions
  - How/if we combine estimates across the network? More research is needed to determine best practices

- Expect iterations and exploratory discovery throughout the process