Background and Objective

- The US Food and Drug Administration’s Sentinel System uses a distributed data network of routinely collected electronic health data, including administrative and claims data, to conduct active surveillance on medical product safety.
- Observable person-time in the indicated population is instrumental to drug safety analyses. While median length of observation time for members in commercial insurance claims databases is <2 years,1 variation by chronic conditions is unknown.
- Our objective was to assess prevalence and duration of follow-up of chronic condition cohorts in the Sentinel Distributed Database (SDD).

Methods

- We identified prevalent and incident cohorts of 24 chronic conditions in the SDD from 2008-2018.
- Follow-up began at the first qualifying diagnosis date and ended at the earliest occurrence of disenrollment, death, or end of data.

Results

Figure 1. Median and Inter-Quartile Range of Duration of Follow-up Time By Prevalent Chronic Condition

Figure 2. Prevalence of Chronic Conditions

Figure 3. Duration of Follow Up Time of Select Prevalent Chronic Conditions by Sex, Age, and Data Partner (DP) Type

Methods (continued)

- We operationalized the Centers for Medicare and Medicaid Services (CMS) Chronic Conditions Data Warehouse (CCW) condition algorithms2 by:
  a. Mapping the claim type and diagnosis position requirements into the Sentinel Common Data Model care setting and diagnosis position options.
  b. For most conditions, members were required to have evidence of ≥1 inpatient or 2 ambulatory claims with qualifying diagnosis codes.
  c. Conditions were defined using International Classification of Diseases, 9th and 10th revisions, with clinical modification. The US transitioned to ICD-10-CM codes on October 1, 2015.
- Using the algorithm reference period as the lookback period when multiple claims are required.
- Applying the algorithm reference period as the washout (no evidence of prior diagnosis) and enrollment requirement periods for the incident cohort.
- Applying co-existing exclusion diagnosis codes at encounter level.

Conclusions and Limitations

- Median follow-up ranged from 0.8 (lung cancer) to 2.7 years (hyperlipidemia).
- Conditions with shorter follow-up time had a higher proportion of members censored due to death (55% vs 11% for lung cancer vs hyperlipidemia).
- Proportion of members censored due to disenrollment or end of data was consistent across conditions.
- The proportion of members with >2 years follow-up time ranged from 17% (lung cancer) to 45% (glaucoma, hyperlipidemia, and osteoporosis).
- Incident cohorts had similar follow-up, with a few exceptions (median follow-up 2.4 vs 1.7 years for prevalent vs incident ischemic heart disease cohorts).
- Hypertension and hyperlipidemia had the highest prevalence (26.3% and 23.9%), while all 5 cancers assessed had low prevalence (0.2-1.5%).

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