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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

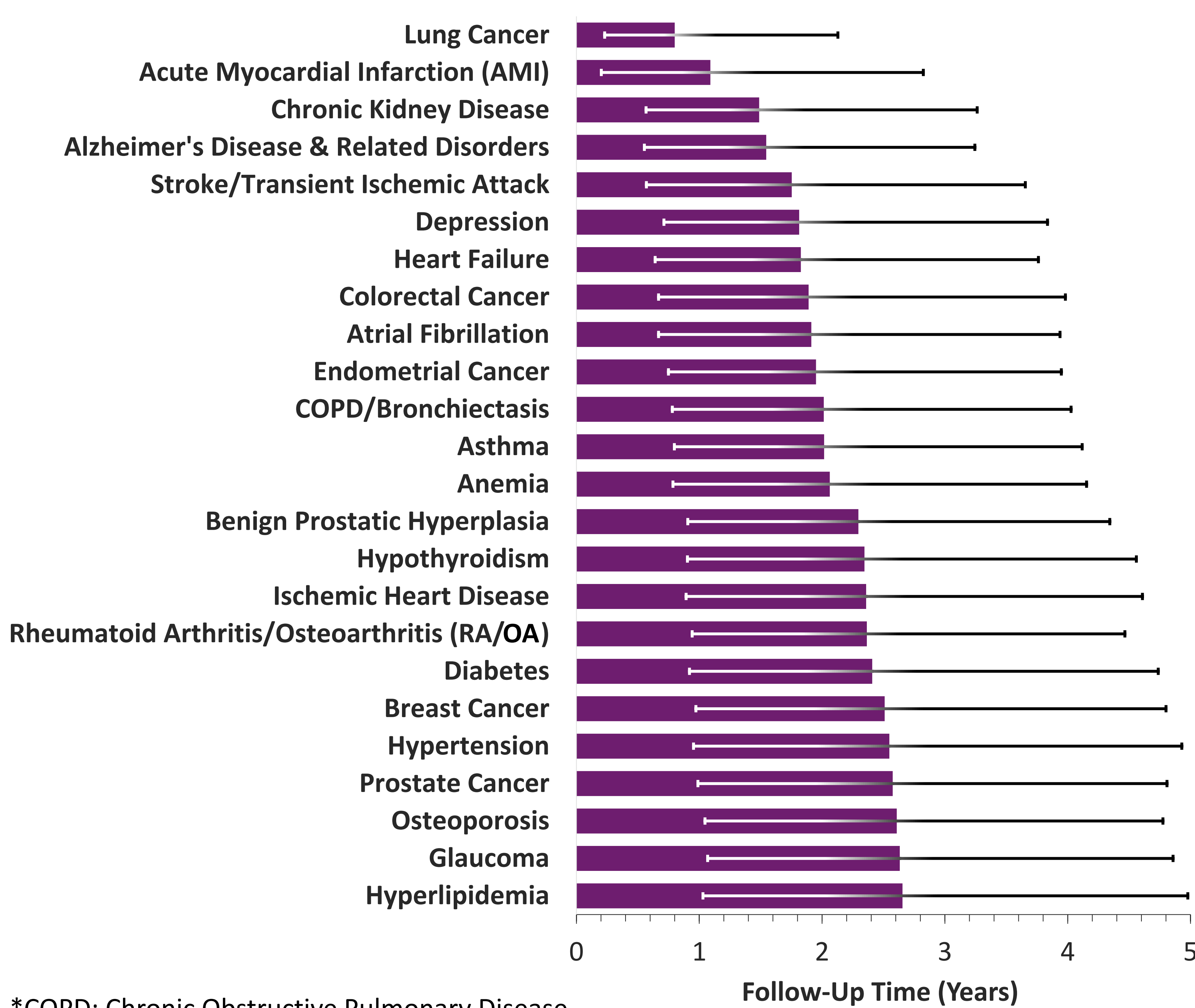
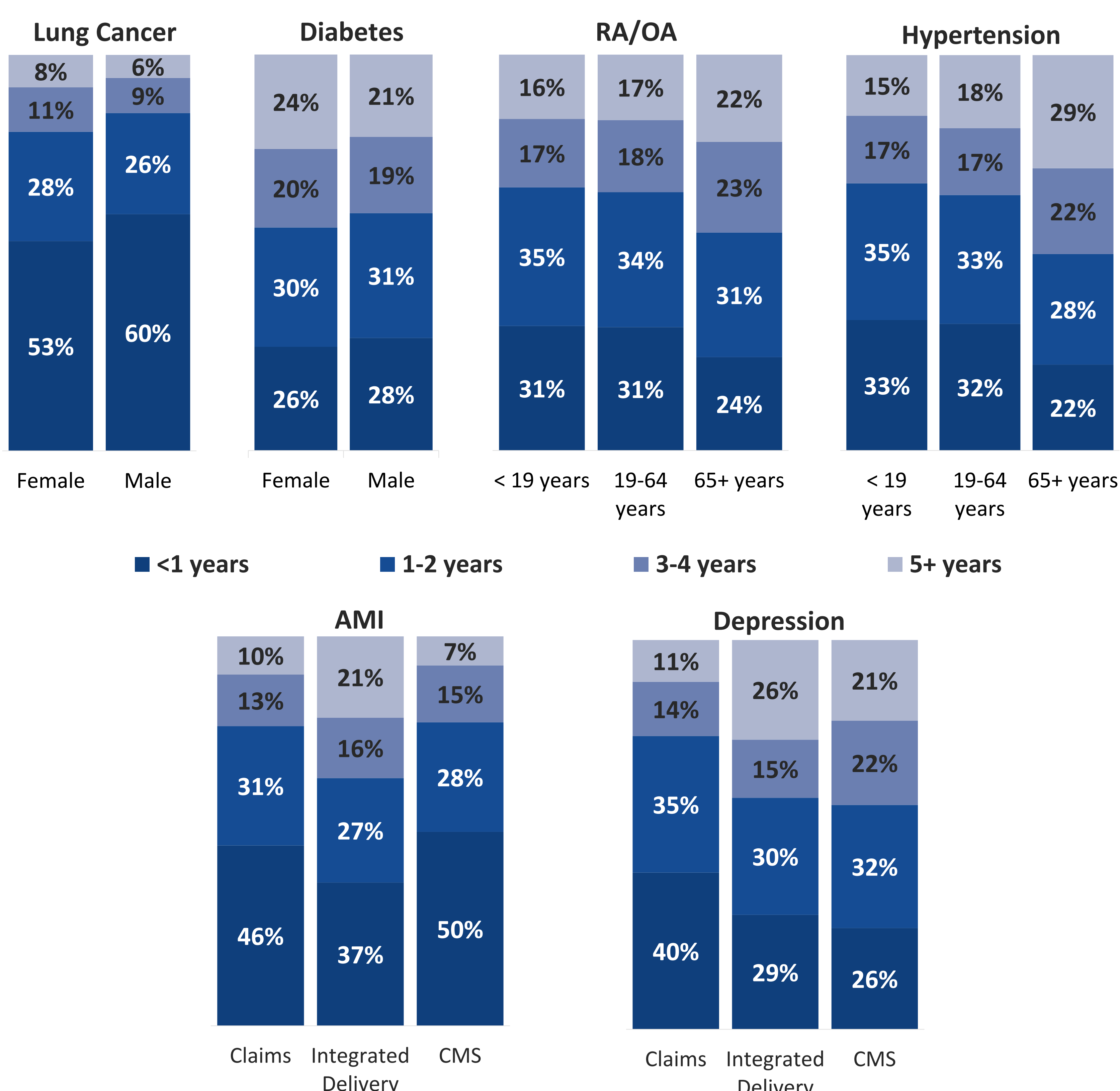


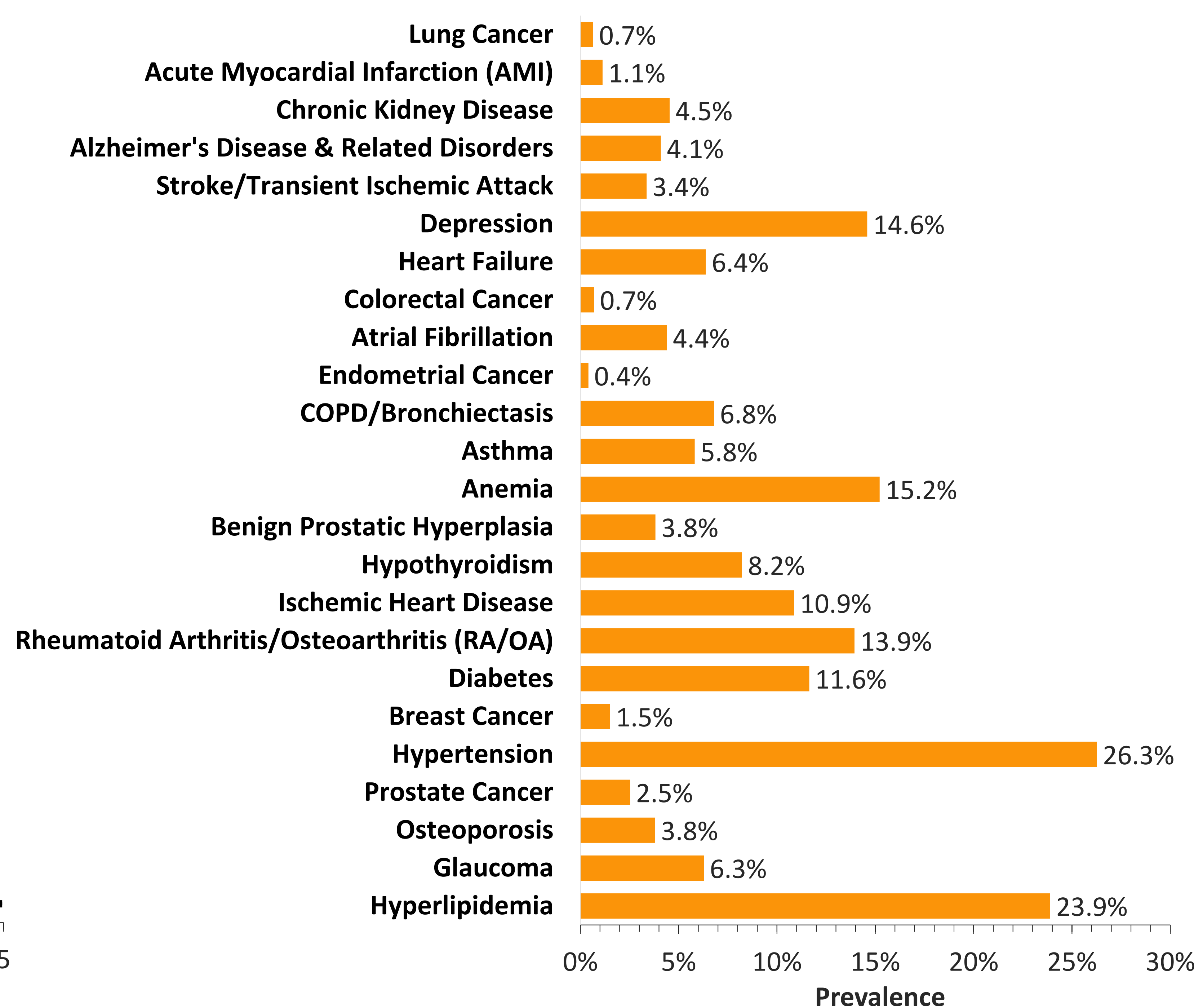
Figure 3. Duration of Follow Up Time of Select Prevalent Chronic Conditions by Sex, Age, and Data Partner (DP) Type



Methods (continued)

- We operationalized the Centers for Medicare and Medicaid Services (CMS) Chronic Conditions Data Warehouse (CCW) condition algorithms² by:
 - Mapping the claim type and diagnosis position requirements into the Sentinel Common Data Model care setting and diagnosis position options.
 - For most conditions, members were required to have evidence of ≥ 1 inpatient or 2 ambulatory claims with qualifying diagnosis codes.
 - 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.
 - Using 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.

Figure 2. Prevalence of Chronic Conditions



- 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 in 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%).

Conclusions and Limitations

- Studies that assess the safety of drugs used to treat chronic conditions in claims data require indicated patient cohorts to have adequate follow-up time to observe outcomes of interest.
- SDD may provide sufficient person-time to observe many outcomes of interest in claims-based drug safety evaluations in chronic condition patient cohorts, though this ability will vary by chronic condition, patient age, and data type.
- We observed shorter follow-up times among some conditions with higher mortality, but the relationship between censoring reason and follow-up time warrants further exploration.
- CCW algorithms are widely used to characterize the Medicare population, although they have not been fully validated. The generalizability of these algorithms to the non-Medicare population is unknown.

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- Many thanks are due to Data Partners who provided data used in the analysis.
- The authors have no conflicts of interest to disclose.

¹ Jensen ET, Cook SF, Allen JK, et al. Enrollment factors and bias of disease prevalence estimates in administrative claims data. *Ann Epidemiol.* 2015;25(7):519-525.

²Chronic Conditions Data Warehouse. Condition Categories - Chronic Conditions Data Warehouse. <https://www.ccwdata.org/web/guest/condition-categories>.