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Comparability Assessment of Cohorts with and without Laboratory Values

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Abstract

Studies of clinical cohorts using US administrative claims data have found individuals who receive lab tests differ from those without lab tests, leading to incorrect cohort characterization. This study compared characteristics of patients with and without lab tests ordered within claims-based clinical cohorts and identified substantial differences between those subjects without a laboratory test, with a laboratory test regardless of the value, and with a laboratory test and an associated value. We recommend that researchers using laboratory data examine differences in populations with and without laboratory tests to avoid biasing their study.

Introduction:

Laboratory values provide valuable information for characterizing patients with a new condition diagnosis or drug use. However, studies using US administrative claims databases have found that organization- and patient-level factors can influence whether a laboratory test is ordered, received, and recorded in claims data. Organizational-level factors influencing availability of lab test values include linkage of claims to specific national lab test providers, which excludes lab values obtained from other lab providers.(1) Additionally, patients may be more likely to receive lab tests if they need diagnostic or monitoring work for disease risk factors, drug use, or other comorbidities(2-4) or if they exhibit health-seeking behaviors.(5) As a result, meaningful lab values may only be available for certain cohort subpopulations and may not accurately reflect true lab values of all patients in the clinical cohort.

This study sought to assess comparability between patients with and without laboratory tests, specifically amongst hyperlipidemic, non-type 2 diabetic statin users with and without low density lipoprotein cholesterol (LDL-c) measurements and with and without measurement values. Although not presented here, we plan to illustrate this effect is various cohorts.

Methods:

This study used the OptumInsight SES database converted to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), version 5.01. Cohorts were developed using the OHDSI Atlas tool. Four cohorts were generated; subjects without a laboratory measurement; subjects with a laboratory measurement; subjects with a laboratory measurement and an associated value, and subjects with a laboratory measurement and no associated value. All cohorts required: subjects 18 years and older, an initial diagnosis and at least one prior confirmatory diagnosis 365 to 180 days before index, and continuous observation of at least 365 days before the index event. Laboratory values were evaluated in the 180 days prior to index date.

Users of statins were defined as subjects with prescriptions of drugs containing the following ingredients: pitavastatin, Lovastatin, Cerivastatin, sodium sitagliptin, Pravastatin, Fenofibrate, fluvastatin, atorvastatin, Simvastatin, ezetimibe, Niacin, rosuvastatin, Perindopril, Ramipril, Amlodipine, Aspirin. LDL-c laboratory measurements were defined using LOINC, SNOMED, CPT4, and HCPCS codes and included panel and non-panel measurements.

Cohort comparisons were made by calculating the standardized difference in means for all covariates in units of the pooled standard deviation. The expression for calculating the pooled standard deviation is presented in Austin(6) and is suitable for dichotomous variables and is not influenced by large sample sizes. Plots were generated comparing cohorts with and without laboratory measurements and values in the 180 days prior to the index date comparing absolute standardized mean differences.

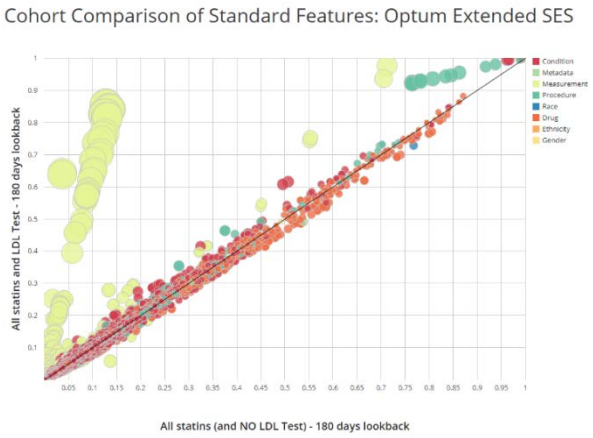
Results:

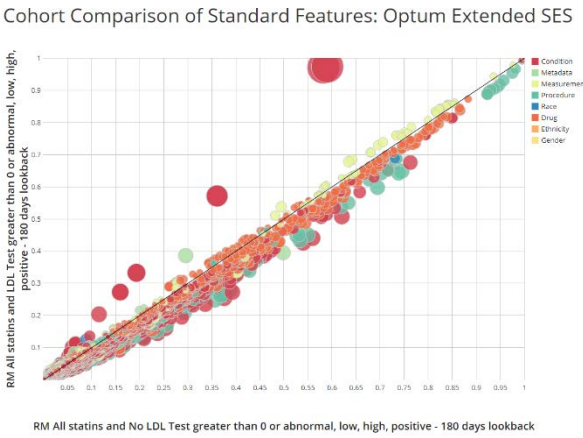
Figure 1 illustrates the comparison of 52,082 covariates between subjects prescribed a statin with (y axis) and without (x-axis) a LDL-c test. We identified 1.1% (N=580) of the covariates with an absolute standardized difference in means > 0.1 (36 condition; 4 drug; 517 measurement; 22 procedure; 1 ethnicity). The largest absolute standardized differences by domain

occurred in the measurement(2.79- Measurement record for the verbatim concept observed during 365d on or prior to cohort index: 3007070-Cholesterol in HDL [Mass/volume] in Serum or Plasma), procedure(0.45- Procedure occurrence record for the concept or any its descendants observed during 365d on or prior to cohort index: 4332170-Venipuncture), and condition(0.23- Condition occurrence record for the concept or any its descendants observed during 30d on or prior to cohort index: 432867-Hyperlipidemia) domains.
Figure 2 illustrates the comparison of 31,046 covariates between subjects prescribed a statin with a LDL-c measurement (x-axis) and a value and those without a value (y-axis). We identified 1.9% (N=590) of the covariates with an absolute standardized difference in means > 0.1 (243 condition; 109 drug; 63 measurement; 173 procedure; 1 race; 1 person). The largest absolute standardized differences by domain occurred in the condition (1.06-Condition occurrence record for the concept or any its descendants observed during 30d on or prior to cohort index: 432867-Hyperlipidemia), procedure (0.23-Procedure occurrence record for the concept or any its descendants observed during 365d on or prior to cohort index: 4078460-Cardiovascular investigation), person (0.21-Index month: 1), drug (0.18- Drug era record for the concept or any its descendants observed anytime on or prior to cohort index: 21600960-ANTITHROMBOTIC AGENTS), measurement(0.16- Measurement numeric value above normal range for latest value within 180d of cohort index: 3028288-Cholesterol in LDL [Mass/volume] in Serum or Plasma by calculation), and race(0.12- Persons by race: race = Black or African American) domains.

Conclusion:
This analysis identified differences in cohorts of subjects with and without measurements (Figure 1) and with measurements with and without values (Figure 2). The cohorts comparing cohorts of subjects with a LDL-c measurement with and without a value illustrate larger differences than cohorts comparing subjects with and without LDL-c measurements. When using measurements to define cohorts, we suggest thoroughly examining the underlying cohorts for comparability.

Figures 1 & 2. Statin users without a LDL-c test compared to statin users with a LDL-c test (1); Statin users with a LDL-c test and value compared to statin users with a LDL-c test and no value in the 180 days prior to the index date.





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