Statistical Analysis Plan

Project Title: Claims-Based Adherence Analysis for Oral Antihypertensive Medications

Sponsor/Client: AxMed Consulting

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Background

Cardiovascular disease remains the leading cause of death in the United States, with statin therapy being a cornerstone in the prevention of major cardiac events, particularly among individuals with diabetes and hypertension. Despite strong clinical evidence supporting the efficacy of antihypertensive medications, adherence remains suboptimal. Racial and ethnic disparities in medication adherence have been well documented and are associated with increased morbidity and mortality.

Real-world pharmacy claims data provide a valuable resource to evaluate adherence patterns and identify demographic disparities that may inform patient outreach and intervention programs. This study aims to assess adherence to oral antihypertensive medications and evaluate differences in adherence rates by race and ethnicity.

Objective

The purpose of this analysis is to evaluate medication adherence patterns among patients prescribed oral antihypertensive medications using simulated pharmacy claims data. The analysis aims to calculate and summarize key adherence metrics:

- Proportion of Days Covered (PDC)
- Medication Possession Ratio (MPR)

Additionally, the study will identify demographic factors associated with low adherence, with a specific focus on race and ethnicity. This project is intended to support real-world evidence (RWE) insights for healthcare clients.

Data Source

The dataset used in this analysis is a simulated claims dataset created based on publicly available specifications and standard adherence calculation practices by a commercial generative AI model. It includes ~950 unique patients with pharmacy claim records for a single antihypertensive medication between January 1, 2023, and December 31, 2023.

Study Design

This is a retrospective claims-based analysis using prescription fill data to calculate adherence metrics over the defined observation period.

- Study Period: January 1, 2023 to December 31, 2023
- Inclusion Criteria: Patients with at least two prescription fills for the same medication during the study period and a minimum 180-day observation window.

Definitions

- Observation Period: Defined per patient as the span between the first fill date and the end date of the last fill (based on fill date + days' supply), inclusive.
- PDC (Proportion of Days Covered):

$$PDC = \frac{Total\ Covered\ Days}{Observation\ Period\ (Max\ 180\ days)}$$

Overlapping days between fills are not double-counted.

- MPR (Medication Possession Ratio):

$$MPR = \frac{Total\ Days\ Supplied}{Observation\ Period\ (Max\ 180\ days)}$$

Overlaps are allowed in the numerator.

- Adherence Flag: Patients are considered adherent if PDC ≥ 80% (0.80).

Variables Collected

- Patient ID

- Age

- Sex

- Race/Ethnicity

- Fill Date

- Days Supply

- Medication Name

- NDC Code

- Payer Type

Statistical Methods

- Descriptive Statistics:

  - Mean, median, and standard deviation for PDC and MPR

- Distribution histograms

- Adherence rates (PDC ≥ 80%) overall and stratified by:

  - Age Group

  - Sex

  - Payer Type

  - Race/Ethnicity

- Inferential Analysis:

  - Logistic regression to identify predictors of non-adherence (PDC < 80%)

  - Covariates: Age, Sex, Payer Type, Race/Ethnicity

Software
- Programming Language: SAS

Deliverables
- Cleaned and labeled analysis dataset

- Adherence summary tables

- Stratified metrics by demographic subgroups (including race/ethnicity)

- Regression analysis results

Assumptions and Limitations
- The dataset is simulated; real-world variability and missingness may differ.

- Assumes consistent medication dosing and no treatment discontinuation not captured in the dataset.

- External factors (e.g., hospitalizations, medication switches) are not accounted for.

Confidentiality
This analysis is based on synthetic data and does not contain any personally identifiable or protected health information (PHI).

Data Dictionary

Variable Name	Description	Type	Example

patient_id	Unique identifier for each patient	Categorical	P001
fill_date	Date the prescription was filled	Date	2023-04-15
days_supply	Number of days the prescription should last	Numeric	30
sex	Reported sex of patient	Categorical	M / F
age	Patient age at time of first fill	Numeric	56
race_ethnicity	Race or ethnicity of the patient	Categorical	Hispanic
payer_type	Type of insurance coverage	Categorical	Medicare
medication_name	Name of the antihypertensive drug	Categorical	Lisinopril
ndc_code	National Drug Code of dispensed medication	Categorical	00093-1048
pdc	Proportion of Days Covered	Numeric	0.84
mpr	Medication Possession Ratio	Numeric	1.02
adherence_flag	Binary flag for PDC ≥ 80%	Categorical	Yes / No