Introduction

- Angiotensin-converting enzyme inhibitors (ACEi) are a risk factor for angioedema, particularly in Black patients.
- Angioedema is generally a rare event. Most clinical cohorts do not have sufficient sample size to evaluate outcomes.
- Master protocols for parallel analyses across multiple sites have been used to study rare outcomes.
- Key to such analyses is understanding of differences in exposure and transparent reporting.

Methods

- The planned study is a population-based, retrospective, multicenter cohort study of adult patients with HF identified from two networks: 1. IMEDS, a subset of the US Food and Drug Administration Sentinel Network System Network, using data from January 1, 2008 through September 30, 2019. 2. CVRN, which includes patients seen at the integrated healthcare delivery systems across the US, starting from July 1, 2008 through September 30, 2019.
- Both networks provide broad representation across the US, including a diverse population of patients with commercial insurance coverage.
- Outcomes and exposures are identified through claims in both networks. Primary outcomes included any (any setting) and serious (inpatient setting) angioedema.
- To adapt an integrated EHR+claims-based protocol to claims only, we:
  - Outcomes and exposures are identified through claims in both networks.
  - Primary investigators for their contributions and review of this poster.

Results

- Open up review of interim results and many future conversations.
- ACEi and CVRN aligned on approaches for the final analysis to define medication exposure that considered the clinical context (acute onset adverse events) and we agreed on an approach that is predominantly reactive (ie, half of the dispersion), which was different than the standard approach taken in IMEDS and Sentinel, and shorter than what CVRN initially proposed.
- CVRN aligned with CVRN on the approach for the final analysis.

Objective

- To address sample size issues, the Innovation in Medical Evidence Development and Surveillance (IMEDS) Network and Cardiovascular Research Network (CVRN) collaborated on an approach originally developed for electronic health record (EHR) data linked to administrative claims data.
- Although both networks leveraged pharmacy administrative claims to one using claims only to assess angioedema risk in HF patients with HF identified from two networks:
- Researchers for their contributions and review of this poster.

Table 1. Characteristics for patients with heart failure on ACEi.

Table 2. Incidence of serious and any angioedema in patients taking ACEi.

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References

5. The ability to agree to disagree.