Organization Information

Organization Name

Select "Other" if your organization is not listed.

Zeenat Qureshi Stroke Institutes

Project Information

Project Title

Cardiovascular Event Rates in Patients with Treated Hypothyroidism and Established Atherosclerotic Cardiovascular Disease using the Massachusetts All-Payer Claims Database

Primary Investigator - Name

Adnan Qureshi

Primary Investigator - Title

Professor of Neurology

Project Details

Please provide a detailed description of each of the following project components.

Describe your Project's purpose and the specific need for CHIA Data.

Non-government applicants: You must include your methodology or attach your methodology as a separate document.

The purpose of this study is to quantify real-world cardiovascular event rates among patients with treated hypothyroidism and established atherosclerotic cardiovascular disease (ASCVD) using the Massachusetts All-Payer Claims Database (APCD). The analyses will inform feasibility, sample size assumptions, and external validity for a planned randomized cardiovascular outcomes trial targeting residual thrombotic risk in hypothyroidism.

Hypothyroidism is a highly prevalent chronic endocrine condition and is associated with increased risks of myocardial infarction, ischemic stroke, and coronary revascularization. Despite thyroid hormone replacement therapy, residual cardiovascular risk persists, and no treatment is currently approved to reduce cardiovascular events specifically in this population.

Specific Aims:

• Estimate incidence rates of major cardiovascular events (myocardial infarction, ischemic stroke, coronary/carotid revascularization) among adults with treated hypothyroidism and established ASCVD.

• Quantify the prevalence of treated hypothyroidism among patients with ASCVD in Massachusetts and assess the proportion meeting high-risk enrichment criteria (e.g., diabetes, chronic kidney disease, polyvascular disease).

• Estimate bleeding-related hospitalization rates in this population.

Describe your Project's intended outputs (e.g., internal or external reports, publications, or other products).

The primary intended output is a peer-reviewed manuscript reporting incidence rates of major cardiovascular events (myocardial infarction, ischemic stroke, and coronary/carotid revascularization) and bleeding-related hospitalizations among Massachusetts adults with treated hypothyroidism and established atherosclerotic cardiovascular disease. Secondary outputs include aggregate summary tables and statistical analyses to support sample size calculations and feasibility assessment for a planned randomized cardiovascular outcomes trial. Findings will also be presented at national scientific conferences. All outputs will be reported at the state level in aggregate form, in full compliance with CHIA's cell-size suppression policy.

This project serves the public interest because it will use Massachusetts APCD data to measure the prevalence of treated hypothyroidism and the real-world rates of major cardiovascular and bleeding events among Massachusetts residents age 45 and older with established atherosclerotic cardiovascular disease. Hypothyroidism affects approximately 4.6% of the U.S. adult population, translating to an estimated 300,000–320,000 Massachusetts residents. Cardiovascular disease is the leading cause of death in Massachusetts, accounting for more than 14,000 deaths annually. Among patients with established ASCVD, hypothyroidism is associated with a 20–40% higher risk of recurrent cardiovascular events compared to euthyroid patients, yet no treatment is currently approved to specifically reduce this residual risk. Patients with ASCVD and hypothyroidism also incur disproportionately higher hospitalization rates, contributing significantly to Massachusetts healthcare expenditures.

The project aligns with CHIA's public-interest standard because it is a health cost and utilization analysis that can inform public policy, support population health improvement, and guide health system planning. By identifying the burden of illness and real-world event rates in this population, the study will improve care quality, identify higher-risk subgroups, and directly support the design of a randomized cardiovascular outcomes trial, with findings to be disseminated through peer-reviewed publications and scientific presentations.

Do you intend to use generative Artificial Intelligence (AI) for this Project or expose CHIA Data to generative AI?

No

Data

What type of Data are you requesting?

APCD

Feasibility of Using De-Identified Data

Please explain why your Project is not feasible using De-Identified Data. In your explanation, include specific elements that are not available in the De-identified Data Set, but that are required for your Project. Your explanation should meet the requirements set forth in 45 CFR 164.508. **Indicate N/A if you are requesting De-identified Data.**

N/A

Specify the years of APCD Data you are requesting.

CHIA is supporting requests for APCD Data from 2020-2024. Do not request Data from years that are not included within the available scope. Requests made outside those years will not be fulfilled.

2018-2024 (LM amended to 2020-2024 on 3.3.26)

Are you requesting Medicaid Data?

Requests for Medicaid Data will require additional review by MassHealth, the Medicaid plan for Massachusetts. MassHealth must approve the request before CHIA can provide Medicaid Data. All applicants requesting Medicaid Data must review the terms of the Medicaid Addendum to the Data Use Agreement, which contains the terms and conditions upon receiving Medicaid Data.

No; I am not requesting Medicaid Data

Select the APCD files you are requesting.

Medical Claims

Pharmacy Claims

Provider

Member Eligibility

Explain why you require the selected APCD Data Files

☒ Medical Claims
Describe how your research objectives require Medical Claims data:

- Inpatient and outpatient data will help identify the incidence of cardiovascular events such as myocardial infarction and ischemic stroke.

- Medical claims are required to identify the study population and ascertain all primary and secondary outcomes. Inpatient and outpatient diagnosis codes (ICD-10-CM) will be used to define hypothyroidism, established ASCVD, and

comorbid conditions (diabetes, chronic kidney disease, polyvascular disease). Procedure codes (CPT/HCPCS) will be used to identify coronary and carotid revascularization events, and inpatient claims will be used to capture hospitalizations for myocardial infarction, ischemic stroke, and bleeding-related events.

Diagnosis Codes:

- Hypothyroidism, ASCVD, myocardial infarction, stroke, and bleeding events to identify the study population and relevant outcomes.

☒ Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

- Thyroid hormone replacement and antiplatelet agents' data are required to study treatment patterns and associated risks in patients with treated hypothyroidism.

- Pharmacy claims are required to confirm treated hypothyroidism, defined as ≥2 dispensing claims for thyroid hormone replacement therapy (e.g., levothyroxine). Pharmacy data will also be used to identify use of antiplatelet agents and anticoagulants, which are relevant to both outcome ascertainment and the exclusion of patients on therapeutic anticoagulation for atrial fibrillation or venous thromboembolism.

☒ Member Eligibility

Describe how your research objectives require Member Eligibility data:

- Member eligibility files are required to define continuous enrollment periods, establish the study-eligible population, calculate person-time at risk, and ensure that outcome events occur during active coverage. Eligibility data will also provide demographic information — including age and sex — needed for descriptive analyses and subgroup stratification.

☒ Provider

Describe how your research objectives require Provider data:

- Provider data are requested to characterize the care settings in which study-eligible patients receive cardiovascular and endocrine care. This will support contextual interpretation of event rates across provider types and geographic regions within Massachusetts.

Data Linkages

Non-government entities typically are not permitted to link CHIA Data to another source at the individual patient level. If an applicant wishes to link CHIA Data to another source at the individual patient level, CHIA may, in its sole discretion, perform custom linkage work for the applicant. In doing so, CHIA may also charge linkage service fees. Data linkage work performed by CHIA will substantially increase the time it will take for applicants to receive the requested Data.

Will CHIA Data be linked to or merged with another data source?

No

Publication / Dissemination / Re-Release

Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Additionally, as detailed in the Data Use Agreement, CHIA must be provided with an advance copy of any publication or report derived from CHIA Data.

Do you intend to disseminate the results of your analysis publicly?

Yes

How do you intend to disseminate the results of the analysis (e.g. professional journal, newsletter, webpage, etc.)?

Peer-reviewed publication in a cardiovascular neurology or endocrinology journal; oral or poster presentations at national scientific conferences (American Heart Association, American Stroke Association, American Academy of Neurology, American Thyroid Association); and internal regulatory presentations to support cardiovascular outcomes trial planning.

Do you intend to disseminate the results of your analysis internally within your Organization?

No

Do you intend to use CHIA Data as an input to develop or sell a product (e.g. severity index tool, risk adjustment tool, reference tool, etc.)?

No

Do you intend to resell CHIA Data?

No