Protocol

Developing Robust Antiobesity Medication Implementation Approaches to Maximize Population Health: Protocol for the DOMINO Study

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Abstract

Background: Despite robust evidence supporting the efficacy of antiobesity medications (AOMs), their use remains limited and inequitable across populations. Patient, provider, and system-level barriers constrain equitable AOM use in eligible persons, limiting the cumulative health benefits realized by eligible patients.

Objective: Guided by the tailored implementation for chronic diseases (TICD) framework and implementation mapping (IM), the DOMINO (Developing Robust Antiobesity Medication Implementation Approaches to Maximize Population Health) study aims to identify determinants of AOM use, obtain stakeholder input, and develop an implementation road map to guide payers, health systems, and prescribers in supporting equitable and appropriate clinical use of AOMs.

Methods: The DOMINO study begins with a data-driven needs assessment, followed by qualitative interviews to assess contextual factors, and then stakeholder-guided selection of strategies to address barriers and contextual factors, resulting in an IM approach. Aim 1 evaluates AOM prescribing patterns and determinants of use using electronic health record data from 3 southeastern US health systems. Demographic, clinical, and provider characteristics of AOM users and nonusers will be compared. Cox regression will estimate time from first eligible BMI to AOM initiation, incorporating time-varying covariates and calendar-year fixed effects; secondary analyses will assess repeated use, duration, and medication switching. Aim 2 uses the TICD framework to guide approximately 90 semistructured interviews with patients, providers, health system leaders, and payers to identify multilevel barriers and facilitators to AOM adoption. Our analytic approaches will allow for both deductive and inductive insights to identify salient determinants. Aim 3 will use findings from aims 1 and 2 to develop an AOM implementation road map. Determinants will be prioritized by importance and feasibility, mapped to implementation strategies, and refined through advisory panels using acceptability, feasibility, effectiveness, cost-effectiveness, side effects or unintended consequences, safety, and equity criteria to enable future hybrid trial testing.

Results: The DOMINO study was funded in April 2024. Preliminary data obtained prior to submitting the grant application indicated significant variability in the number of AOM users, the number with a glucagon-like peptide-1 (GLP-1) prescription, and race/ethnicity demographics. Electronic health record (EHR) data extraction from the 3 health systems was completed in April 2026; data cleaning and preparation of analytic datasets are underway. As of August 2026, aim 2 included 40 patient interviews, 5 payer interviews, and 14 provider interviews. Aim 3, including advisory board panels, is anticipated to begin in late 2026. Publication of results is expected by June 2028.

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Conclusions: This study will generate an empirically derived, partner-driven road map for implementing AOM use. By addressing operational barriers, workflow integration, and patient affordability, DOMINO will produce scalable tools and processes for health systems to optimize obesity care and advance equity in obesity management.

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KEYWORDS

antiobesity medication; AOM; appropriate use; implementation; obesity

Introduction

Background

From 1960 to 2020, the proportion of Americans with obesity (BMI ≥30 kg/m^2) more than tripled from 13% to 41.9%, with severe obesity (BMI ≥40 kg/m^2) increasing tenfold from 0.8% to 9.2% [1-6]. Obesity is associated with significant morbidity, including an increased risk for type 2 diabetes, hypertension, heart disease, cancer, and osteoarthritis [7]. These obesity-associated conditions are a leading cause of preventable, premature death in the United States, accounting for approximately 112,000 deaths per year [8]. Health care expenditures attributable to obesity prevalence and associated conditions in the United States have increased from US $70 billion in 1995 to US $173 billion in 2019 [9-11]. These trends highlight the urgent need to promote healthy weight across the US population, as surgical and behavioral interventions alone have not reversed the obesity epidemic.

In 2021, the US Food and Drug Administration (FDA) approved the glucagon-like peptide 1 (GLP-1) receptor agonist semaglutide and, in 2023, the GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonist tirzepatide. These and more recent antiobesity medication (AOM) approvals are ushering in a radical shift in the treatment of obesity [12,13] because they produce more weight loss than prior AOMs and are poised to become essential tools in population weight management. In clinical trials, patients receiving a once-weekly semaglutide injection of 2.4 mg experienced an average weight loss of 15% within 1 year, with 77% of patients achieving clinically significant weight loss of greater than or equal to 5% [12,14]. Notably, trial patients receiving daily tirzepatide 15 mg achieved a weight loss of 21% within 1 year, with 91% of patients achieving greater than or equal to 5% weight loss [15]. Table 1 presents a concise overview of the effectiveness, safety, and costs associated with FDA-approved AOMs based on recent systematic reviews [13,16-18].

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Table 1. Weight loss efficacy, side effects, and costs of FDA[a]-approved AOMs[b] [13,15-17].

AOM (year of FDA approval)	Mean weight loss and proportion with ≥5% weight loss	Common and rare side effects	Cost per month (as of June 2023; US $)
Tirzepatide (2023)	15%-20.9% at 72 weeks (depending on dose); 85%-91% achieved ≥5% weight loss	• Common: nausea, vomiting, and constipation • Rare: pancreatitis	1200-1500
Semaglutide (2021)	15.2% at 104 weeks; 77% achieved ≥5% weight loss	• Common: nausea, vomiting, and constipation • Rare: pancreatitis	1100
Liraglutide (2014)	8% at 56 weeks; 63% achieved >5% weight loss	• Common: Nausea, vomiting, constipation; Rare: pancreatitis	1090
Naltrexone-bupropion extended release (2014)	3% at 56 weeks. 41% achieved ≥5% weight loss	• Common: headache, dizziness, nausea, vomiting, depression, and increase in blood pressure that resolves by 12 weeks in RCTs[c] • Rare: seizure, cholecystitis, and suicidal ideation	300-500
Phentermine-Topiramate-Extended Release (2012)	7%-11% at 12-24 months (depending on dose), 74% achieved 7%-11% weight loss [19]	• Common: same as phentermine + paresthesia, dysgeusia, and cognitive dysfunction • Rare: same as phentermine + glaucoma and nephrolithiasis	100-150
Orlistat (1999)	2.8% at 48 weeks to 4 years; 59% achieved ≥5% weight loss	• Common: flatulence, oily stools, fecal urgency, and fecal incontinence • Rare: liver failure	50-60
Phentermine (1959)	7%-10% at 6 months (RCT); 7% at 24 months (observational study)	• Common: dry mouth, insomnia, constipation, anxiety, and headache • Rare: elevated blood pressure and heart rate	5-20

[a]FDA: US Food and Drug Administration.

[b]AOM: antiobesity medication.

[c]RCT: randomized controlled trial.

Despite their clinical benefits, we still lack a clear understanding of how to implement AOMs equitably and effectively in everyday practice, particularly given high costs and access constraints. The current environment creates critical disparities in access to AOMs for lower-income and underinsured patients, underscoring the need for timely real-world evidence on patterns and disparities in AOM use. Further, the high unit cost of these injectable medications, recent (December 2025) FDA approval of oral semaglutide, the large pipeline of new AOMs, and new federal pricing policy create uncertainty in a dynamic environment that patients, providers, and payers are finding challenging to navigate. Our study aims to address evidence gaps by identifying best practices, barriers, and strategies that address barriers to AOM use at multiple levels, including patient, provider, health system, and payer.

Study Objectives

This work will provide a comprehensive characterization of the patterns and predictors of AOM use in 3 large, diverse health systems in the southeastern United States, generating real-world evidence on patient exposure to different AOMs as measured by provider prescribing practices (aim 1). Despite the upward trends in AOM initiation, prior evidence suggests only 1% to 3% of all eligible patients used AOMs as of June 2023, due to a variety of factors, including variable or limited insurance coverage, high out-of-pocket costs, patient and provider concerns about AOM safety, lack of confidence in the long-term efficacy of AOMs, insufficient knowledge of newer AOMs, and time constraints during health care visits [20-33]. These barriers to AOM uptake are described in the literature and outlined in Table 2. Long-standing stigma toward patients with obesity likely plays a role as well [34-39]. Interventions to address these critical barriers to AOM uptake are urgently needed to integrate AOMs more fully into clinical practice, as a complement to behavioral interventions and metabolic/bariatric surgery.

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Table 2. Major barriers to use of AOMs[a] in clinical practice in the United States.

Barriers to AOM use	Evidence supporting the importance of the barrier
High cost	• Newer AOMs (eg, liraglutide, semaglutide, and tirzepatide) are expensive, at US $1000-US $1600 per month before insurance [40,41]. • If 10% of eligible patients received semaglutide for obesity through Medicare Part D coverage, it would cost US $13.6 billion annually, equivalent to 9% of Part D spending in 2019 [42].
Low and variable insurance coverage	• AOM insurance coverage in the US is highly variable and not mandatory by law [42-45]. • A 2015-2016 survey of 7378 adults with employer-based insurance found that only 21% had AOM coverage [43]. • As of 2017, only 16 state Medicaid plans covered more than 1 AOM [45]. • Medicare Part D does not cover any FDAb-approved AOMs, but Medicare Advantage plans can cover AOMs via enhanced alternative coverage as a supplemental benefit if enrollees are willing to pay the higher premiums [46]. In 2017, Medicare Advantage plans paid only 555 claims for AOMs (GAO-19-577). • A 2019 Government Accountability Office report found that two-thirds of all AOM spending was for out-of-pocket payments by patients (GAO-19-577).
Safety concerns	• The US Drug Enforcement Administration schedule lists phentermine and phentermine-topiramate extended-release as Schedule IV medications because the chemical structure of phentermine is similar to that of amphetamines, which have the potential for abuse and addiction. • Clinicians may be concerned about AOM side effects due to past recalls of drugs like fenfluramine (increased risk of valvular heart disease and pulmonary hypertension), sibutramine (increased risk of stroke and myocardial infarction), and lorcaserin (linked to cancer) [33,47]. • A recent obesity guideline states that the potential harms of AOMs are greater than those for lifestyle intervention alone [48]. • Long-term safety of newer AOMs is not well understood [49,50].
Low provider knowledge of AOMs	• Providers have inadequate knowledge of AOM treatment guidelines. Only 8% of 1506 primary care providers surveyed could correctly identify the criteria for starting and continuing AOMs [51]. • Educational interventions may enhance clinical knowledge of obesity and its treatment options, leading to increased comfort in prescribing AOMs [52].
Weight stigma and bias	• Health care professionals, including physicians, nurses, students, and nutritionists, hold biases against people with obesity, believing that it is primarily caused by poor behavior. Even obesity specialists surveyed at a 2013 conference revealed such biases [36-39]. • Clinician biases have real consequences for patient care, including reluctance to prescribe AOMs due to perceiving patients with higher BMI as having lower medication adherence [35]. • In recorded visits, clinicians provide less empathy and reassurance to patients with higher BMI [34].
Clinical practice variation	• There is wide variability in AOM prescribing across individual clinicians and clinics [22,23,53]. • In 2010, AOM prescription rates for US veterans with obesity varied from 0% to 21% across 140 Veterans Health Administration facilities [22]. • In an 8-site retrospective cohort study of over 2 million enrollees eligible for AOMs in 2009-2015, 89.6% of all AOM prescriptions were written by 8.3% of health care providers [23]. • Some clinicians are prescribing medications off-label (eg, generic phentermine and topiramate or generic bupropion and naltrexone separately; Ozempic instead of Wegovy for patients without diabetes) in an attempt to provide greater access to these medications.
Incretin mimetic (GLP[c] and GIP[d]) shortages	• There have been nationwide shortages of incretin mimetics including GLP1-RAe and dual GLP-1/GIPf agents as they have grown in popularity. • Shortages have caused disruption in treatment for obesity and diabetes [54]. • Celebrity promotion, off-label use and cosmetic use may have contributed to increased demand.

[a]AOM: antiobesity medication.

[b]FDA: US Food and Drug Administration.

[c]GLP: glucagon-like peptide.

[d]GIP: glucose-dependent insulinotropic polypeptide.

[e]GLP-1 RA: glucagon-like peptide-1 receptor agonist.

[f]GLP-1/GIP: glucagon-like peptide-1/glucose-dependent insulinotropic polypeptide.

While these barriers appear well characterized, most of this evidence is based on older studies that predate the introduction of the incretin mimetics (GLP-1 and GIP), which appear to have significantly impacted public, provider, and payer perceptions of the utility of AOMs, as expressed in news reports [19,55]. In the DOMINO (Developing Robust Antiobesity Medication Implementation Approaches to Maximize Population Health) study, we will evaluate system-specific patterns of AOM access

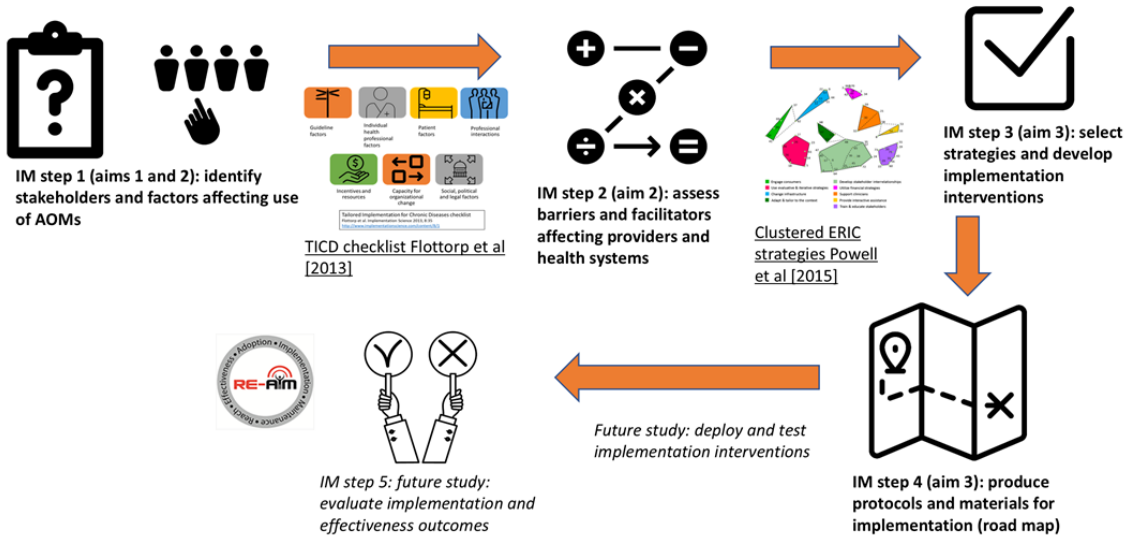
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that span the incretin mimetic era to understand current facilitators and barriers to AOM provision (aim 1). We will then conduct interviews with patients, providers, health system leaders, and payers to understand their perspectives on access and affordability (aim 2). Aim 2 interviews and aim 1 results about patient access will inform the design of an AOM implementation road map (aim 3) for selecting and guiding implementation strategies that can be tailored to local barriers and facilitators to enable health systems to optimize patient access to AOMs. A detailed study timeline is provided in Multimedia Appendix 1.

Conceptual Model

The conceptual framework (Figure 1 [56,57]) informing this study is implementation mapping (IM) [58], a rigorous process that integrates theory, empirical evidence, and stakeholder input to develop strategies to enhance intervention adoption, implementation, and sustainability. The targeted evidence-based intervention is increasing appropriate AOM use. We will complete steps 1 through 4 in IM to develop implementation strategies, with plans to deploy and test them in a future project. In steps 1 and 2, we will use the tailored implementation for chronic diseases (TICD) framework [56], which is the most current consolidated determinants (barriers and facilitators to implementation success) framework in the implementation research literature.

Figure 1. Implementation mapping using the TICD and implementation mapping.



Methods

Overview

The first step in IM is to identify stakeholders and participants in implementation by role and undertake a needs assessment. Aim 1 in our study will include identifying key stakeholders—patients eligible for AOM use, providers who prescribe AOMs, and relevant health system leaders. The second IM step (aim 2) involves identifying desired outcomes, such as more equitable AOM access, and their determinants intended to increase implementation success. In the third IM step (aims 2 and 3), we will identify implementation strategies expected to achieve desired outcomes, tailoring the strategies to health care organizational contexts based on input from key stakeholders to produce the AOM implementation road map (IM step 4). We show this in Figure 1.

Experienced Multidisciplinary Study Team

The project is a continuation of long-term collaborations by a multidisciplinary team representing Duke University (MLM and VAS), Kaiser Permanente Washington (DEA, CH, and RM), the University of Missouri (AES), Vanderbilt University Medical Center (SBD), and Wake Forest (KHL).

Stakeholder Advisory Board

A Stakeholder Advisory Board will be convened at study start and then annually to provide feedback on the detailed development of the work plan for each aim. This feedback is critical because the portfolio of AOMs and strategies of payers to address these changes are likely to be highly dynamic. For our work to be most responsive to these changes, we will seek guidance from the SAB to ensure that our planned work generates results that are most useful to these diverse stakeholders interviewed in aim 2. The SAB will be composed of volunteers from the patient, provider, health plan leadership, and payer groups.

Population and Setting of Analytic Cohorts

We will conduct a longitudinal retrospective cohort study in aim 1 involving adult patients (aged ≥18 years) from these 3 health systems from 2014 to 2024 who were eligible for AOMs,

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corresponding to BMI greater than or equal to 30 kg/m^2 or BMI greater than or equal to 27 kg/m^2 with obesity-related comorbidity (eg, diabetes). We will identify all AOM prescriptions. The study period starts in 2014 to identify how characteristics of patients prescribed AOMs may be changing over time. We will include older adults (≥65 years) and younger adults (18-25 years), as these populations have not often been included in prior studies of AOMs. Inclusion criteria include having at least 1 height measurement and 2 or more weight measurements that correspond to the BMI criteria above. There will be no exclusion criteria because the goal of this study is to characterize real-world use of AOMs with the greatest possible generalizability. In the 3 sites, we expect to identify over 250,000 patients with obesity from 2014 to 2024 who are eligible for AOMs, of whom more than 35,000 will have been prescribed 1 or more AOMs in this period. The index date for all patients will be the date of the first eligible BMI recorded in each health system's electronic health record (EHR) data in the study period (2014-2024). For those prescribed AOMs, a subsequent key date will be the order date for the AOM first observed.

Core Data Sources

Beginning in January 2014, the Patient-Centered Outcomes Research Institute funded 11 Clinical Data Research Networks (CDRNs, including the Science, Technology and Research Partnership (STAR) network) to develop the Patient-Centered Outcomes Research Network (PCORnet), an infrastructure to "create a large, highly representative, national network for conducting clinical outcomes research" [59]. During phase 1 of this work, these CDRNs created a common data model (CDM) that is consistent across each CDRN (Table 3). Unlike centralized data repositories, the CDM consists of parallel databases set up identically at each CDRN site that can be easily queried and merged across sites. Each CDRN has a different number of participating organizations or "nodes." We will engage 3 STAR network nodes (Duke University Health System, Wake Forest Baptist Health, and Vanderbilt University Medical Center) to participate in aims 1 and 2.

Table 3. CDM[a] data tables that are applicable to the AOM[b] study.

CDM table	Description	Applicability for AOM study
Demographic	Contains 1 record per patient with key demographic variables.	Age, sex, Hispanic ethnicity (yes/no), race, and insurance type are captured.
Encounter	Contains 1 record for each time a patient sees a provider in an ambulatory setting or is hospitalized; multiple encounters per day are possible if they occur with different providers or settings.	Encounter type will be used to identify specialties of providers seen previously. Deaths that occur during a hospital stay will be captured in the discharge status variable.
Diagnosis	Contains all uniquely recorded diagnoses for all encounters. Each diagnosis is associated with a specific patient and encounter.	Diagnosis codes and associated encounter dates will be used to establish medical history before AOM order in study period.
Procedure	Contains all uniquely recorded procedures for all encounters. Each procedure is associated with a specific patient and encounter.	Procedure codes and associated encounter dates will be used to identify bariatric surgery and other surgery dates.
Vital	Contains 1 record per height or weight result/entry. Multiple measurements per encounter are recorded as separate measures.	Part of the eligibility criteria and aim 1 outcome: height and weight are captured for BMI.
Medications	Contains 1 record per ordered medication. Multiple orders per encounter are recorded separately.	AOM outcome of interest; other medications for comorbid conditions.

[a]CDM: common data model.

[b]AOM: antiobesity medication.

We selected these sites based on population diversity, wide variability in AOM use, and completeness of CDM data tables. A data mart within each node in the STAR network has been constructed by extracting data from local EHR databases from participating organizations and reconfiguring those data into CDM data tables using standard variable names and coded values [60]. Using the CDM avoids most redundant preparatory work that would otherwise be needed to assemble cohorts or count potential events and other end points. Table 3 above describes the specific data elements in the CDM that will be used to accomplish each study aim. Table 4 also provides further detail on data analysis.

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Table 4. Variables for AOM[a] outcome or covariates expected to be possible predictors of AOM use.

Variable	Source (CDM[b] table)	Rationale
Age	• v6.1 DEMOGRAPHIC table	Medication choice may vary with age
Baseline BMI	• v6.1 VITAL table; Field Names = HT, WT • (date of measurement: Field Name = MEASURE_DATE for each measure)	Baseline BMI may shape patient and providers' medication choice
Comorbid conditions	• v6.1 DIAGNOSIS table; Field Name = DX • v6.1 CONDITION table; Field Name = CONDITION	Comorbidities may impact probability of prescribing an AOM, medication choice
Sex	• v6.1 DEMOGRAPHIC table; Field Name = SEX	Choice of medication may vary with sex
Race/ethnicity	• v6.1 DEMOGRAPHIC table; Field Name = RACE or HISPANIC	Medical treatment choices often vary with race/ethnicity
Baseline smoking status	• v6.1 VITAL table; Field Name = TOBACCO	Smoking status may influence medication choice
Number of prior ambulatory care visits	• v6.1 ENCOUNTER table; Field Name = ENC_TYPE (if AV or OA)	Count of ambulatory visits or other ambulatory visits in prior year
Insurance	• V6.1 ENCOUNTER table; Field Name = PAYER_TYPE_PRIMARY	Insurance via commercial, Medicare, Medicaid, other, uninsured
Provider ID and specialty	• v6.1 PROVIDER table; Field Name = PROVIDER_SPECIALTY_PRIMARY	Specialty of providers seen during ambulatory care visits
AOMs	• v6.1 PRESCRIBING table; Field Name = RXNORM_CUI, RAW_RX_NDC	Medication exposure of interest

[a]AOM: antiobesity medication.

[b]CDM: common data model.

Preliminary Data

In preparation for grant funding and prior to submitting the grant application, we conducted a query through PCORnet to obtain aggregate data on the utilization of AOMs in these health systems (Table 5). There was significant variability in the number of AOM users, the number with a GLP-1 prescription, and race/ethnicity demographics.

Table 5. Preliminary data on AOM[a] users in STAR[b] network sites included in this study, from 2009-2022.

Characteristic	Duke	Wake Forest	Vanderbilt
AOM users, n	21,724	10,545	3888
GLP-1[c] users, n	9603	7154	1991
Age (years), mean	45.5	45.1	44.5
Age (years), n (%)			
18-44	10,210 (47)	4956 (47)	1982 (51)
45-64	9993 (46)	4913 (47)	1594 (41)
≥65	1303 (6)	627 (6)	311 (8)
Female, n (%)	18,900 (87)	9069 (86)	3188 (82)
Black or African American, n (%)	6734 (31)	1687 (16)	544 (14)
Hispanic, n (%)	869 (4)	316 (3)	78 (2)
White, n (%)	13,252 (61)	8225 (78)	3072 (79)

[a]AOM: antiobesity medication.

[b]STAR: Science, Technology and Research Partnership.

[c]GLP-1: glucagon-like peptide-1.

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Aim 1: Data Analysis

Primary Outcome

For aim 1, the primary outcome is AOM use—overall and by specific AOM type—at each STAR network site. We will consider both on-label and off-label use for this outcome. For example, we will identify patients without diabetes who are receiving Ozempic, which would be off-label use of this medication (the formulation of semaglutide indicated for treatment of diabetes). For regression analyses, our primary outcome is time to first AOM use from the index date. Secondary outcomes include the dose and days' supply per order for each AOM, the total days' supply across all orders for each AOM, the number (and proportion) of patients switching between AOMs in the first year following prescribing of any AOM, and the duration of exposure (number of days ordered) from the first AOM order until switching to the second AOM. We will also examine the proportion of primary care providers and specialists who prescribed AOMs 1 or more times and examine whether a subset of prescribers account for a disproportionate share of all AOM orders. We provide details of the drug codes and covariates planned for analysis in Table 5.

To assess varied patterns of AOM use, we will compare baseline demographic and clinical characteristics, prior health care use, and provider characteristics (specialty; AOM ordering behavior) yearly via standardized mean differences between AOM users and nonusers. We will then identify the demographic, comorbidity, prior health care use, and provider factors associated with AOM use via Cox regression.

Definition of Covariates

Aim 1 analyses will rely on EMR data derived from the STAR network's CDM, as summarized in Table 3 and Table 5. Continuous variables include age, BMI, and comorbidity score. We will generate indicators for the 37 unique physical and mental health conditions of the Gagne score, which was derived by combining conditions from the Charlson and Elixhauser measures that have been externally validated among Medicare enrollees and is predictive of 30-day, 90-day, 180-day, and 360-day mortality [61]. These indicators will be constructed based on primary or secondary diagnosis codes. Individual physical and mental health conditions have been linked with weight change, so it will be important to identify specific conditions associated with AOM use. Categorical patient-level variables include race/ethnicity, sex, smoking status, insurance status, number of outpatient visits in the prior year, and specialties of providers seen during these visits (primary care, endocrinologist, psychiatrist, and other). Time-varying covariates will be updated on a rolling monthly basis and any time an individual has a visit in order to capture changes over time that may influence AOM uptake. We will include sex as a predictor to assess the effect of sex as a biological variable.

Analytic Plan for AOM Use: Continued

Project analysts at the prime site for this project will write a query program based on the CDM data dictionary. The query program is then sent to the other participating nodes in the STAR network to be run locally on each data mart, and the output files are securely transferred to the prime site. At this point, the primary site analysts will undertake an evaluation (or quality control) process that will accompany this study to execute aim 1 and construct final analytic files.

Modeling time from first eligible BMI to first AOM use in our study period, we will allow covariates to update at each visit with a provider (at the date of the visit) and at the first of each month for anyone without a visit in that month. Time-varying covariates, described above, and calendar year fixed effects will be included to assess associations with AOM initiation. By allowing the updating of covariates, we will capture with greater precision any patient and provider changes that may directly lead to the decision to initiate AOMs.

To consider patients initiating multiple, separate episodes of AOMs instead of just the first, we will conduct a secondary analysis with a binary indicator in each calendar year of the study indicating whether a patient was ordered an AOM from 2009 to 2023 via logistic regression with random effects for each individual to account for repeated yearly observations. Among STAR network patients with one or more AOM orders, we will describe the unadjusted number of orders per person for each AOM, mean and median days' supply per order, and mean and median total days' supply over all orders in the first year after AOM initiation. We will also examine the proportion of patients who switch to another AOM within 1 year of the initial AOM order. Then, we will examine patient characteristics associated with the number of medication orders in the year after initiation via count data models (zero-truncated Poisson or negative binomial), adjusting for demographic and clinical characteristics and cost-sharing for AOMs as described above.

Analytic Plan for Provider Identification

To identify whether there is a subset of primary care providers (internists and family medicine), endocrinologists, obstetric/gynecologists, psychiatrists, emergency medicine providers, cardiologists, and other specialists who are super-prescribers of AOMs, as found in prior work [24], we will identify the specific providers in each health system that prescribed 1 or more AOMs in each year of the study period. Descriptively, we will evaluate the proportion of eligible patients receiving AOMs by year and provider type, and the composition of which AOMs are prescribed by each and whether use is on- or off-label. Missing data will be assessed for the quality of missingness. In cases where we assess that data are missing completely at random, we will use casewise deletion to include only full cases. When we assess that there may be systematic reasons for missingness, we will attempt to complete cases with the last known instance of the missing data or impute using multiple imputation methods. We expect that lab values are most likely to be missing, and we will use the last known value when possible.

Power Calculations

Aim 1 is primarily descriptive and exploratory in nature, seeking to clearly characterize the patterns and determinants of AOM use across 3 large health systems. Therefore, power calculations are not appropriate or necessary because there is not a single explanatory variable of interest but instead numerous

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demographic, clinical, and provider characteristics to explore and describe.

Aim 2

Overview

For aim 2, we will identify key factors influencing AOM use at the patient, provider, and systems levels. To accomplish this, we will interview patients (aim 2A), providers and health system leaders (aim 2B), and payers (aim 2C; our original proposal included the plan to include employers among the group to be interviewed. However, due to cuts in both the budget and the timeline after funding was approved, we decided that we will not interview employers) in a wide variety of practices and settings. These determinants of implementation success and other key contextual factors can then inform the design of our aim 3 AOM implementation road map.

Aim 2A: Patient Goals and Inclusion Criteria

To understand patient attitudes, beliefs, and real-world barriers and facilitators to accessing AOMs, we will conduct in-depth, individual qualitative interviews with patients eligible for AOMs. Eligibility criteria include adults aged 18 years or older; BMI greater than or equal to 30 kg/m^2 or BMI greater than or equal to 27 kg/m^2 with obesity-related comorbidity; and receiving care in a primary care, endocrine, or obesity/weight management clinic at Kaiser Permanente Washington or one of the STAR network sites in aim 1. We will use a maximum diversity sampling approach, recruiting patients from a variety of sources. We aim to recruit racial and ethnic minorities, people with a spectrum of experiences with AOMs (those who have and have not used AOMs), and people of different ages and genders. Eligibility is limited to individuals aged 18 years or older since pediatric obesity issues, particularly among younger children, are different from those of adults, and few AOMs are currently approved for children. Due to the exploratory, idea-generating nature of this aim, we will limit our sample to approximately 40 patients, which we believe will be sufficient to generate salient themes to guide aim 3. Our focus in this project is to develop provider- and system-facing interventions. Because of the wide range of experiences and needs of patients, developing patient-facing interventions (eg, patient decision aids) is outside the scope of this study.

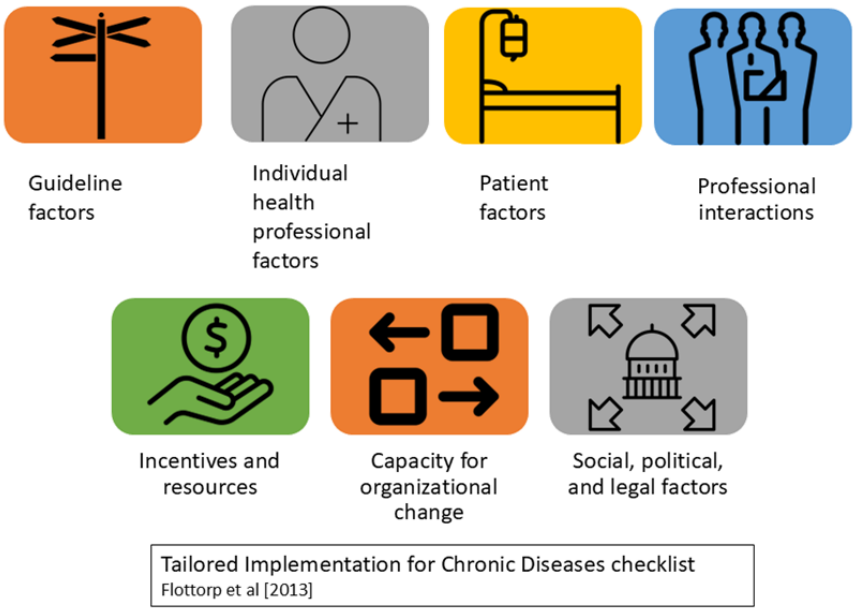
Aim 2A: Recruitment Process

Patient participants will be recruited using posters and postcards distributed in clinics. Recruitment materials will have a QR code that will direct interested patients through an online screening process where they will answer a series of questions to determine variability and gather demographic information to guide purposeful sampling.

Aim 2A: Data Collection Approach

We will use an interview guide designed using the TICD [56] framework (Figure 2 [56]) and modified to focus on patient concerns. Patient interview guide domains will include patient factors (experiences, needs, knowledge and beliefs, motivation and behavior, family and caregiver influence, and emotional factors), guideline and evidence factors (research, education, and information), and social, legal, and political factors. While we have particular interest in barriers to using AOMs, we are also interested in possible facilitators, including awareness of health risks, prior successful weight loss, prior interactions with providers about AOMs, social support, and other factors. We expect our patient interviews to take 45 to 60 minutes. We will conduct patient interviews by phone. Interviews will be recorded and transcribed. Patient participants will receive monetary compensation for participating.

Figure 2. TICD checklist domains.



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Aim 2B: Provider and Leader Goals and Inclusion Criteria

We will interview health care providers and health system leaders to understand referral processes, attitudes, beliefs, and current practices from their perspectives, including attitudes toward AOMs, general views on obesity among patients, and barriers and facilitators to prescribing AOMs. Using data from STAR network sites in aim 1, we will identify and recruit both high- and low-AOM-prescribing providers. We will focus on clinical leaders in the health systems, particularly those overseeing primary care and weight management services, which may include both medications and surgery. Our focus in this study is AOMs, but we recognize the frequent overlap between surgical and medical services.

Aim 2B: Recruitment Process

We will identify providers in each health system participating in aim 1 by assessing provider AOM prescribing volume relative to the size of their patient panels. Our goal is to recruit at least 8 providers (4 high-prescribing and 4 low- or nonprescribing) and 2 health system leaders in each health system in aim 1. We will recruit providers through email contacts after obtaining health system leadership buy-in. We will identify health system leaders who have oversight over prescribing providers and responsibility for development and use of electronic health record resources, such as service line chiefs, associate chiefs of staff, and associate chief medical informatics officers. We will recruit them through initial contact with the local site investigator, followed by a phone call with one of the core coinvestigators.

Aim 2B: Data Collection Approach

Our interview guide, based on the TICD, will cover all 7 domains, focusing on issues related to intervention factors. These issues include guideline factors, including injectable delivery mode and safety concerns; individual health professional factors, including attitudes and beliefs about obesity as well as about the medications and other bariatric treatment modalities; patient factors, focusing on provider perceptions of factors affecting patient decisions; professional interactions, including referral patterns and team processes; incentives and resources, including any incentives and disincentives for prescribing AOMs; capacity for organizational change, including perspectives of leaders, regulations and policies, priority of necessary change, and assistance for any needed organizational change; and social, political, and legal factors, focusing especially on cost, payment, and insurance issues. We anticipate that our interviews will take approximately 30 minutes [56]. These interviews will be conducted via Zoom (or other videoconference platform) or phone and recorded and transcribed for analysis.

Aim 2C: Payer Goals and Inclusion Criteria

We will conduct individual interviews with a stakeholder group comprising regional payers and national payers involved in AOM policy and reimbursement (our updated protocol, following funding approval and cuts to the budget and timeline, no longer includes employer interviews) to understand attitudes toward AOM coverage, particularly what kind of economic and effectiveness evidence might be persuasive to improve coverage options.

Aim 2C: Recruitment Process

We will focus on national insurance companies with strong market share in the regions in which the 3 health systems operate, as well as small regional insurers. We aim to conduct 20 interviews, including up to 5 payers across the 3 regions from our 5 academic health systems. We will identify these participants through contacts within the health care sector, including partners in political advocacy and trade associations of health insurance companies.

Aim 2C: Data Collection Approach

The interview guide for payers, based on the TICD, will focus on attitudes, beliefs, and concerns about cost and the health and well-being of the insured. We anticipate these interviews will take 30 to 40 minutes. Interviews will be conducted virtually, as in aims 2A and 2B.

Aim 2: Data Analysis

Our goal in analyzing the data from interviews in aim 2 is to understand the range of barriers and facilitators to using AOMs from the perspective of all major types of stakeholders, as well as to understand the referral processes and health care experiences of patients and providers in navigating systems intended to provide care in relation to the complex area of obesity care. For aims 2A and 2C, we will use a rapid group analysis process, which is a newer, structured 5-step qualitative approach designed to expedite data analysis while maintaining close engagement with the primary data [62]. First, planning and preparation will be led by 1 or more qualitative leads (CH), who define analytic goals, identify key domains, and assemble and train the analysis team. The next step involves individual data engagement, as team members review assigned transcripts and extract salient insights, notes, and illustrative quotes aligned with the TICD domains and emergent themes. The third step involves collaborative group analysis, in which team members convene virtually to share individual observations, cluster similar insights, and collectively refine themes through structured discussion. Fourth, the leads collate and systematize learnings by consolidating group outputs into organized matrices that link themes with supporting quotations to enable auditability from interpretation back to source data. Finally, findings are summarized and synthesized similarly to traditional methods.

For aim 2B, we will use a template analysis approach to code the interview data via Dedoose (SocioCultural Research Consultants, LLC). We will initially use the TICD constructs as a priori codes and add codes that emerge organically from the data. We will train a group of 3 to 4 coders, including 2 research assistants together with AES, using deidentified transcripts from previous projects AES has conducted using similar methods. We will aim to achieve approximately 75% interrater reliability during the training period by meeting regularly to discuss coding differences and develop understanding of the constructs. After training completion, we will code the cleaned, deidentified transcripts from the recorded interviews with 2 coders for each of the first 3 to 5 transcripts from each type of stakeholder. Each coder will code

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independently, with AES and another team member cocoding approximately 10% as quality checks.

Our goal is to develop a list of salient barriers and facilitators for each group of stakeholders, as well as to assess common barriers and facilitators across stakeholder groups and dependencies among barriers and facilitators across groups. For example, a barrier that is likely to cause dependencies across levels is medication cost, which will affect insurers' coverage decisions, which will in turn affect affordability for patients, and this will affect providers' willingness to prescribe the medications.

Aim 3: Developing AOM Use Implementation Road Map

Overview

Based on the findings from aims 1 and 2, we will design an AOM implementation road map that will outline multilevel implementation interventions to increase access to AOMs in ways that maximize population health. This AOM implementation road map will have essential tools to allow for future testing of the implementation model's efficacy. In the future, this intervention development work will be tested in a hybrid design trial [63].

Step 1: Rate Importance of Determinants and Conduct Preliminary Strategy Mapping

As we describe in aims 1 and 2, we will use the TICD checklist [56] to identify key determinants of AOM use. We will then use an approach described by Damschroder and Lowery [64] to rate the determinants on their level of importance and whether they are positive determinants (facilitators) or negative determinants (barriers). Specifically, we will rate each coded determinant from -2 to +2, where -2 denotes a very important negative determinant or barrier, +2 implies a very important positive determinant or facilitator, and 0 implies relative lack of importance. Research team members will undertake this step after coding is complete to ensure that all relevant determinants are considered. Highly salient determinants will be identified through the ratings. The research team will then identify candidate implementation strategies that address highly salient determinants, initially based on the Expert Recommendations for Implementing Change (ERIC) list of strategies [57] and strategies from other sources where the mechanism of strategy action addresses the determinant.

The research team will use the Implementation Research Logic Model [57] approach to associate determinants with implementation strategies [57] by articulating the theory underlying how the strategy will address the determinant (ie, the causal mechanisms of action). For example, "lack of knowledge of own practice" is a frequent, salient negative determinant or barrier to implementing evidence-based practice, which reflects the fact that providers are often unaware of their own practice performance, such as how frequently they prescribe AOMs to eligible patients. A theory-based strategy to address this is an audit of practice, coupled with feedback to providers to enhance understanding of their own practice. Audit and feedback is theorized to work by highlighting the performance discrepancy between actual clinical performance and desired or expected clinical performance.

Step 2: Convene the Stakeholder Advisory Board

We will convene 1 or more virtual panels of stakeholders comprising willing volunteers from the 4 groups of stakeholders participating in aim 2. These panels will review the determinants identified as salient by the research team in the prior step, deciding which salient determinants should be prioritized for implementing improved access and appropriate uptake of evidence-based weight-loss medications. In a subsequent meeting with the same panels of stakeholders, we will then present possible strategies that the research team associated with the high-priority determinants. Using a structured tool, we will ask the stakeholder advisory board (SAB) to rate key attributes of possible implementation strategies using preestablished criteria (APEASE [acceptability, feasibility, effectiveness, cost-effectiveness, side effects or unintended consequences, safety, and equity]) [65].

We anticipate multiple meetings of the SAB throughout the final year of the project. We expect to iterate through the steps described above at least twice, ensuring that all participants representing the major stakeholder groups have an opportunity to express their perspectives and hear the perspectives of other stakeholders. We will convene these groups virtually, keeping each meeting relatively short (1.5 to 2 hours), with materials to review between meetings. We anticipate that individuals will participate in at least 4 meetings, possibly up to 6.

Steps 3 and 4

Between meetings, the research team will collate the outcomes of all the discussions, synthesize and reexamine mappings to strategies. As the second and third rounds of meetings conclude, we will assemble strategies into more fully designed implementation interventions, specifying strategies using the approach developed by Proctor et al [54], and present the developing implementation interventions with fully specified strategies to the SAB at the next meeting to get their feedback and reassessment of the APEASE criteria. We will then assemble the AOM implementation road map, clearly specifying optional components that can be adapted by each health system or clinic within a health system and required core components.

The final meetings will focus on reviewing the AOM implementation road map, with discussion about how each health system would envision deploying it. We will record and transcribe the proceedings of these final meetings and analyze any additional determinants that emerge. We will then make the AOM implementation road map available to the 3 health systems providing aim 1 data for their use.

Ethical Considerations

Ethics approvals have been obtained from Duke University (single institutional review board [IRB] providing oversight for activities at Duke University, Vanderbilt University Medical Center, and Kaiser Permanente Washington; protocol number Pro00118475), the University of Missouri (deemed exempt from IRB oversight; protocol number 2118707), and Wake Forest University (deemed exempt; protocol number

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IRB00117747). We received a waiver of HIPAA (Health Insurance Portability and Accountability Act) authorization from the Duke IRB covering patient data in aim 1. All interviews are conducted as exempt under Exemption Category 2 of the Revised Common Rule, with information sheets distributed and verbal consent obtained prior to conducting the interview. Providers are compensated US $40 for an interview, patients are compensated US $75, and payers US $40. Provider and payer interviews are expected to last 30 minutes at most, while patient interviews may last up to 60 minutes. Interview transcripts are fully anonymized before analysis.

For aim 1, we will use data from 3 health systems participating in the multisite STAR network of the national PCORnet to understand the demographic, clinical, and provider characteristics of eligible patients that are associated with AOM receipt and greater duration of AOM use. Data from the PCORnet STAR network will facilitate investigation of real-world clinical practice patterns related to AOM use in 3 academic health systems with diverse populations located in the southeastern United States. These 3 academic health systems are Duke University Health System, Vanderbilt University Medical Center, and Wake Forest Baptist Health. All patient data are fully deidentified.

Results

Overview

Funding began in 2024. Data extraction from the 3 health systems is complete as of April 2026, and data cleaning and preparation of analytic data sets are underway. As of August 2026, aim 2 has completed 40 patient interviews, 5 payer interviews, and 14 provider interviews. Aim 3, including the advisory board panels, is anticipated to begin in 2026.

Timeline, Administration, and Structure of the Research Team

We anticipated that start-up activities, including obtaining IRB approvals, data use agreements, and development of query code for aim 1 data pulls, would take 3 months to complete (original project timeline in Multimedia Appendix 1; note that the fifth year was cut from the project as part of the funding decision). Quarters 2-4 will be spent extracting and cleaning data from STAR network sites. Quarters 5-7 will be spent analyzing aim 1 results and writing aim 1 results and manuscripts. Quarters 8-10 will be spent conducting aim 2A, 2B, and 2C interviews with patients, providers, health system leaders, payers, and employers, respectively. Quarters 10-13 will be spent transcribing, analyzing, and writing up interview results, and writing aim 2 manuscripts and materials to be disseminated to stakeholders.

Quarters 14-18 will be spent presenting the materials to stakeholders and developing AOM use road map materials, reviewing with stakeholders, and iterating materials to generate their final versions. Quarters 18-20 will be spent writing aim 3 manuscripts, abstracts, and the final report. The SAB will be convened in quarter 1 to orient them to the proposed study and obtain suggested changes to the study plan. In addition, they will be convened in the third quarter of each year to review study progress and more detailed plans for subsequent work. The Duke team will convene coinvestigators and consultants for conference calls bimonthly. An experienced research project manager will schedule all project meetings and manage regulatory (IRB) issues.

Discussion

Principal Findings

The DOMINO study is designed to address an important implementation gap in the use of AOMs. We anticipate that this study will identify multilevel determinants of AOM use spanning patient, clinician, organizational, and health system contexts and will translate these findings into a practical implementation road map. Importantly, the study is not intended to establish the clinical efficacy of individual AOMs but to identify factors that influence whether evidence-based AOM treatment can be appropriately accessed, prescribed, initiated, and sustained in routine clinical care.

By integrating health system data with qualitative perspectives from patients, clinicians, and other relevant stakeholders, DOMINO is expected to provide a more comprehensive understanding of the barriers and facilitators influencing AOM use than could be obtained from either approach alone. The combination of real-world prescribing patterns and stakeholder perspectives may help distinguish gaps in AOM use that reflect patient preferences or circumstances from those arising from clinician practices, organizational workflows, medication access, or broader structural barriers. These findings will inform development of a timely implementation road map that is intended to be responsive to the realities of contemporary obesity care.

A particularly important anticipated contribution is the identification of opportunities to improve equity in AOM use. Access to obesity treatment may be influenced by medication cost, insurance coverage, availability of clinicians with obesity management expertise, geographic access to care, and differences in patient and clinician perceptions of obesity and its treatment. Examining these factors across diverse populations and health care settings may identify implementation strategies that can address modifiable barriers while recognizing that AOM use is shaped by factors extending beyond individual patient or clinician behavior.

Comparison With Prior Work

Prior research has established the effectiveness of AOMs for weight reduction and, for several agents, improvements in cardiometabolic and other health outcomes [12-18]. However, evidence of clinical efficacy does not necessarily translate into equitable uptake in routine practice. Implementation of AOMs occurs within complex health care systems in which prescribing decisions may be influenced by medication availability, insurance coverage, cost, clinician knowledge and confidence, competing clinical priorities, organizational workflows, and patient preferences. Thus, understanding the gap between what is clinically possible and what occurs in practice requires an implementation-focused approach.

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Existing studies have examined individual barriers to obesity treatment and AOM use, including stigma, treatment perceptions, affordability, insurance restrictions, and limited access to obesity-focused care [4,32-39,42-49]. However, these factors do not operate independently. A patient may be clinically eligible for an AOM but unable to obtain it because of insurance restrictions; alternatively, medication may be accessible but not offered because of clinician uncertainty, competing demands, or limitations in clinical workflows. The TICD framework provides a structure for examining these interacting determinants across multiple domains, while IM provides a systematic approach for translating identified determinants into implementation strategies [56,58]. By combining these approaches, DOMINO seeks to move beyond describing barriers toward identifying actionable opportunities for implementation.

The study also responds to the rapidly evolving nature of obesity pharmacotherapy. The AOM landscape continues to change as new formulations, indications, and therapeutic options become available. Consequently, implementation barriers identified for one medication or treatment era may not fully represent the barriers encountered as treatment options expand. Incorporating newly approved AOMs into stakeholder discussions as appropriate will allow the qualitative components of the study to remain responsive to changes in clinical practice and may help identify implementation needs that extend beyond any single medication.

Limitations, Challenges, and Mitigating Strategies

First, the rapidly changing landscape of AOMs will likely result in the introduction of oral semaglutide and new AOMs during the course of the study. We will introduce any new AOMs into our conversations with stakeholders whenever they become approved by the FDA to help ensure that our findings are timely and relevant to future care delivery. Second, the 3 health systems from which we will extract data for aim 1 and use as sampling frames for aims 2 and 3 are all academic health systems affiliated with highly research-intensive universities. As a result, there are limits to the generalizability and applicability of our findings and implementation road map. However, there are numerous mitigating factors: all 3 health systems are in the southeastern United States with high prevalence of obesity, serving diverse populations, including high- and low-income, racial/ethnic, and culturally diverse populations. Our plans to recruit patients for aim 2A and stakeholders for aim 2C from sites outside these 3 systems will support greater diversity in the voices represented in this study.

Dissemination and Implementation Plan

The study team has developed a robust dissemination strategy based on prior experience with implementation and reporting of health services research. For our research to have an impact, stakeholders (clinicians, patients, and the research community) must be aware of the project from initiation through dissemination, which sets the stage for faster, widespread implementation of research results. To disseminate results to the clinician, health system, and payer communities that we engage in aim 2, we will develop and disseminate an evidence brief summarizing results. In addition, we will develop and disseminate a protocolized form of the AOM implementation road map in aim 3. To the extent possible given resources, we will develop 1 or more plain language summaries to share with interview participants and the public at large via advocacy groups. These may include audiovisual materials such as videos and podcasts narrated by patients and providers to support additional uptake.

Next steps include testing the effectiveness of at least 2 versions of the AOM implementation road map across multiple health systems using a cluster-randomized controlled trial design. These hybrid trial designs [63] were developed specifically to support more rapid implementation of promising clinical and system interventions, allowing generation of evidence for the intervention simultaneously with increasing levels of knowledge about implementation factors. Understanding the effectiveness and side effect profiles for the most common weight-loss medications for different patient populations will likely still be necessary as we conduct this further research, but given the rapid evolution of evidence for these medications, it may be feasible to conduct a hybrid type 3 study with primary outcomes focused on implementation.

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Generative AI Use

The authors declare that generative AI was not used in the preparation of this manuscript.

Authors' Contributions

BAM led the revision of the protocol and drafting of this manuscript from the grant application. AES participated with her in multiple versions of drafting the manuscript. All authors reviewed the manuscript multiple times and provided critical input. MLM, DEA, and AES led the grant application as multiple principal investigators, while all other authors contributed substantially to the grant application as coinvestigators.

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Conflicts of Interest

DEA received an honorarium for speaking and reimbursement for travel from the Obesity Medicine Association for the 2024 Annual Meeting. KHL reports serving on advisory boards for Novo Nordisk, serving as site investigator on an Amgen clinical trial, serving as an invited speaker for Astra Zeneca, serving as Principal Investigator for a clinical trial where study drug was donated by KVK Tech, and serving on the Board of Directors for the American Board of Obesity Medicine.

Multimedia Appendix 1

Study timeline.
[PPTX File , 58 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Peer-reviewer report from the NIH.
[PDF File (Adobe PDF File), 162 KB-Multimedia Appendix 2]

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Abbreviations

AOM: antiobesity medication
APEASE: acceptability, feasibility, effectiveness, cost-effectiveness, side effects or unintended consequences, safety, and equity
CDM: common data model
CDRN: Clinical Data Research Network
DOMINO: Developing Robust Antiobesity Medication Implementation Approaches to Maximize Population Health
EHR: electronic health record
ERIC: Expert Recommendations for Implementing Change
FDA: US Food and Drug Administration
GIP: glucose-dependent insulinotropic polypeptide
GLP-1: glucagon-like peptide-1
HIPAA: Health Insurance Portability and Accountability Act
IM: implementation mapping
IRB: institutional review board
PCORnet: Patient-Centered Outcomes Research Network
SAB: stakeholder advisory board
STAR: Science, Technology and Research Partnership
TICD: tailored implementation for chronic diseases

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