Systems Approach to Evaluation: Anti-Obesity Medications as a Form of Preventative Healthcare

Utilizing a process evaluation and social return on investment analysis to evaluate two online medical weight loss programs: informing healthcare policy change through evidence-based results

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Project Proposal

This evaluation project proposal is in response to the Congressional Budget Office's (CBO) call for new research in the area of obesity. This request was published on the CBO's blog in November 2023. The office is looking for research focusing particularly on the developing market of anti-obesity medications (AOMs). According to the CBO, research that would be the most useful would include factors affecting AOM use, such as take-up rates, patients' adherence to drugs currently on the market, and expectations about the prices and effectiveness of AOMs that are being developed. Research on short and long-term clinical impacts of AOMs, including health benefits or complications associated with them, and their effects on patients' use of, and spending on, other medical services would also be of particular interest.

Currently, federal medical care and private insurers alike do not have policies allowing them to subsidize coverage for prescription medications that prevent / manage obesity specifically. Congress has advocated for The Treat and Reduce Obesity Act 2023 which would change that policy. In accordance, the CBO is asking that "if researchers developed methods to reliably identify cases in which the use of AOMs would substantially lower health care costs in addition to improving health, then policymakers could specify that Medicare cover the drugs in only those cases. Such a policy that targeted an expansion of AOM coverage would result in less federal spending than a policy that broadly authorized coverage of AOMs—though it would be challenging to implement" (Swagel, 2023).

Executive Proposal Summary

Statement of Need: With the dynamic landscape of healthcare policy and recent strides in medical weight loss treatments via virtual platforms, there's an urgent call for a comprehensive evaluation of these online programs to guide policy adjustments concerning Medicare regulations on obesity drug coverage. This evaluation is pivotal for gauging the feasibility, implications, and strategies for implementing Anti-Obesity Medications (AOMs) regarding their long-term effectiveness and cost-effectiveness.

Objective of Evaluation: Understanding the effectiveness of platforms implementing and delivering AOMs is pivotal for assessing the cost-effectiveness of policy changes in healthcare coverage. The primary objective is to comprehensively evaluate online medical weight loss programs through process evaluations of stakeholders. The secondary objective involves incorporating diverse stakeholder perspectives to delineate challenges and identify sustainable solutions. Both phases aim to provide insights into the attribution and contribution of online medical weight loss programs from stakeholders' perspectives.

Timeline: This two-year endeavor is delineated into two phases, each spanning a calendar year, as illustrated in the logic model (Figure 6) of this evaluation project.

Key Evaluative Questions:

1. What is the effectiveness and efficiency of online medical weight loss programs, and can they be enhanced?
2. Should AOMs be covered by insurance for preventative care, and can they serve as effective preventive measures?
3. Will treating obesity lead to reduced costs associated with cardiovascular disease and Type II diabetes?
4. What are the cumulative effects of population-wide weight loss facilitated by online medical weight loss programs, and how can this inform policy

Evaluation Project Design: Phase 1 involves a process evaluation that utilizes an Integrative Systems Framework for Dissemination and Implementation to understand translation, synthesis, implementation, and delivery processes. Data is collected and analyzed in this phase using the evaluative method of Collaborative Outcomes Reporting. Phase 2 comprises a Social Return on Investment Analysis, which provides an economic evaluation of the social, health, and financial value of AOMs from multiple stakeholder perspectives.

Outcome Goals:

1. Enhance the capabilities (efficacy, effectiveness, scope) of online medical weight loss programs (namely, *Calibrate* and *Plenity*) to improve accessibility to healthcare services.
2. Produce a collaborative outcome report and SROI reports that incorporate stakeholder perspectives and empirical evidence that will hopefully influence policymakers, insurers, and the private sector to make policy coverage changes that will subsidize GLP-1s as AOMs as a method of preventive healthcare.

Evaluation Team: Our interdisciplinary team will be divided into three groups. Two groups will focus on supporting the translation, implementation, and delivery of the Calibrate and Plenity programs, while the third group will conduct the Social Return On Investment (SROI) analysis in Phase 2. While team members involved in the participatory process evaluations of Phase 1 will continue their involvement in Phase 2 analysis, they will not directly engage with stakeholders.

I. Context

The Food and Drug Administration approved Semaglutide (commonly known as Ozempic) in 2021 as a way to treat Type II diabetes. The drug belongs to a *growing list* of medications called glucagon-like peptide-1 (GLP-1) receptor agonists, which work to mimic natural glucose regulating hormones. In non-medical terms, Ozempic and other GLP-1 drugs alike work by slowing down "gastric emptying … [which] stimulates insulin release… [thus causing] signals sent to the brain that make you feel less hungry and more full" (Berryhill, Forbes.com). Despite the drug's intended treatment group, its allure for being a weight loss miracle drug has caused it to spike in popularity as a result of the current public health crises centered around obesity. The reality is that, as of 2022, an estimated 70% of Americans were categorized as being overweight or obese per the BMI metric – yet GLP-1 drugs offer a glimpse of relief from that statistic.

However, their popularity is problematic; the drug's coveted nature is coupled with its limited supply, thus fueling shortages of the medication. And while over the last year there have been several new advancements in the field of GLP-1 drug development and subsequent clinical trial testing for getting FDA approval, the supply and demand equilibrium continues to be massively imbalance. For instance, with the FDA granting approval of Wegovy (a GLP-1 medication) on March 8th to treat cardiovascular disease in obese adults, there are now six FDA-approved GLP-1 receptor agonist drugs that have the potential to function as AOMs. The question is, then, why are these drugs not approved for obesity treatment and weight management specifically? Numerous clinical trials have demonstrated their effectiveness at weight loss and weight management, however the current political climate prohibits federal healthcare policy from subsidizing medication costs that are prescribed to treat obesity. Private insurance companies follow suit, as the economic cost is too large to cover independently.

What needs to be assessed in this evaluation is not a clinical evaluation of GLP-1s in particular, but rather an evaluation of the dissemination and implementation of an entire plethora of GLP-1 drugs that are functioning as AOMs – either overtly or inconspicuously. Therefore, this evaluation project will be focused on evaluating a new form of healthcare delivery: online medical weight loss programs (i.e. *Noom Med, Calibrate, Found, RoCo, Plenity,* etc). These virtual platforms are emerging systems within the healthcare services sector and function essentially as a vacuum, connecting millions of individuals to AOM prescriptions either with the help of a primary care physician and/or insurance, or simply through out of pocket costs.

II. Rationale for a Systems approach to Process Evaluation and Economic Evaluation

A central question in the article, *Is Ozempic Enabling Sustainable Consumption?* is whether or not it may actually be the case that, while "researchers and policymakers have been striving – often with underwhelming results – to promote more sustainable consumption, that the pharmaceutical industry has managed to figure out, inadvertently of course, how to slash by significant margins not only food consumption but energy use as well?" (Cohen 2024). To illustrate the extent of population-level

weightloss using a systems approach, consider this statistic theorized by a group of economists from the Washington Post: *"*If enough people lost enough weight using ozempic, it is estimated that the airline industry would save an approximate $80 million on fuel each year" (Gilbert and Reilly 2023). This example highlights the peril of neglecting systemic approaches when confronting the colossal, intricate, and nonlinear issue of individual and population health.

Our team of researchers will employ a systems-based approach for evaluating interventions that utilize anti-obesity medications (AOMs) as a method of reducing obesity prevalence in the United States. A systems approach to evaluating AOM interventions is important for filling a gap in current research on their cost effectiveness at a macro level. We believe that we are a necessary asset for federal-level obesity research specifically because of our systems-based approach to evaluation; the insight we intend to collect through our evaluations will be novel information that is pertinent for both understanding and preparing for unprecedented and unanticipated changes that will undoubtedly occur as more obesity interventions utilize AOMs in their methods.

Most interventions to date have targeted an individual's physiology or behavior around eating or physical activity. And while there are increasing efforts to modify obesogenic settings to effectively reduce excessive caloric consumption and/or insufficient amounts expended, we are still currently in an obesity epidemic: it is estimated that 70% of Americans are overweight or obese. It is painfully obvious that this conventional problem-solving approach for mitigating obesity prevalence has had negligible impacts not only on weight loss but policy change as a whole. Our team is under the impression that AOMs have the potential to actually enable sustainable consumption across industries. Drug manufacturers are sitting on a medication that, if it were to become accessible and ubiquitous to all necessary U.S. populations, could completely transform every facet of daily life, social institutions, and the entire industrial economy as a whole.

III. Seeing & Mapping Systems

It is important to first understand how new methods of intervention and treatment (such as AOMs) fit into the existing body of approaches and frameworks for policy change in government. The figure presented on the following page (figure 1) is a visual model of the framework presented in "The global obesity pandemic: shaped by global drivers and local environments" (Swinburn et al., 2011). Their overarching framework delineates the key facilitators of the obesity epidemic by comparing proximal and distal drivers of weight gain: "The physiology of energy balance is proximally determined by behaviors and distally by environments … Obesity is the result of people responding normally to the obesogenic environments they find themselves in… in the same way, so too do these environments arise because businesses and governments are responding normally to the broader economic and political environments they find themselves in. (Swinburn et al., 2011).

In the same vein, the authors elucidate the interplay between distal systemic drivers that dictate how built environments operate, namely economic and political policies. In figure 1, the "environmental

moderators" refers to different environment conditions between populations. For example, rural versus urban populations have different transportation systems in their built environment; the point is not to compare all different built environments, but to understand in the broader context that individual behaviors are simply condition responses – if an environment promotes low activity (i.e. people rely on cars to get around) and also promotes high consumption (i.e. if there are a lot of fast food businesses per square mile) then overweight populations occur because this is the "normal" condition of their built environment. As illustrated in the restructuring of the Figure 1 diagram, by simply interpreting the old linear model from right to left (i.e. upstream) the order of the processes and causal mechanisms is completely changed when individual physiology is incorporated into the system. By organizing the diagram essentially in a backwards fashion, what became clear is that the actual efficiency and effectiveness of AOMs on a large scale stems from their potential to reverse the overconsumption of food via working on individual physiology. This is beneficial because rebalancing energy intake and energy expenditure must involve reducing intake – this is the only way to return back to an energy equilibrium.

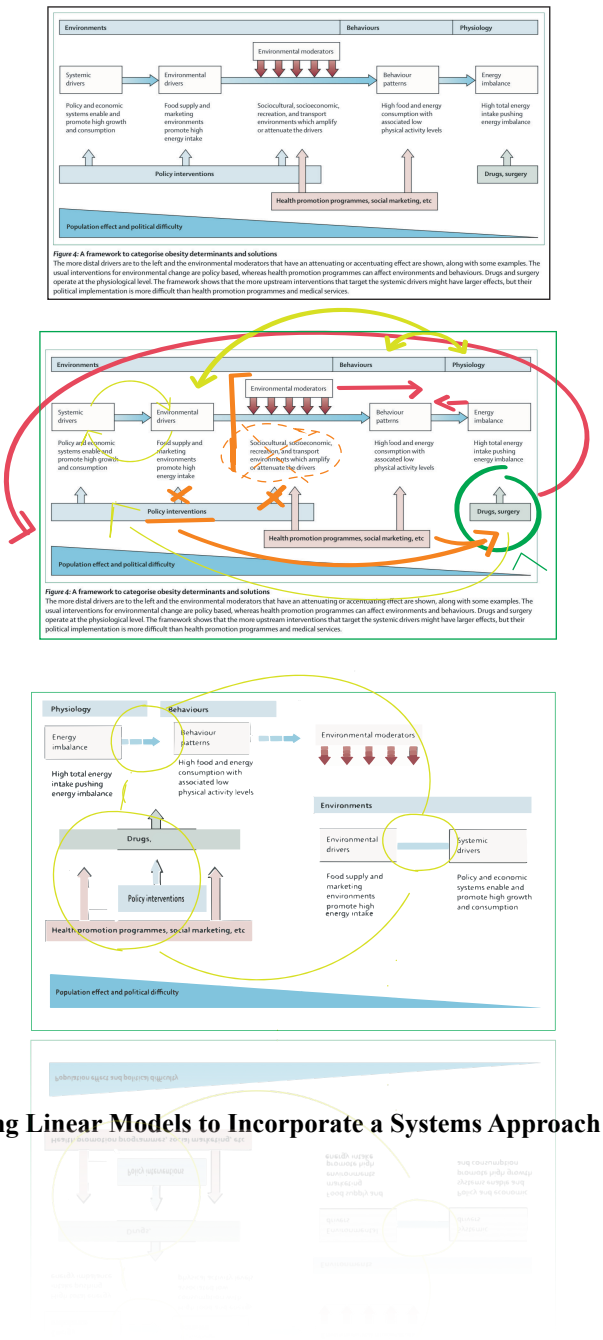

Figure 1. Re-Designing Linear Models to Incorporate a Systems Approach

Power Dynamics between Systems and Actors

	Low power	High power
High involvement / impact	Obese population (all age groups) Diabetic population Hospital patients CDC, WHO, AMA Physicians, Surgeons Nurses, PAs, NPs & other working professionals in the Healthcare industry Telehealth Sector Environmentalists Clinicians , Medical Researchers	-Congress -Lobbyists -Biotech industry -Pharmaceutical industry -FDA State-level health regulatory agencies -Drug manufacturers -Drug Sponsors
Low involvement / impact	Healthy population Those who pay out of pocket for AOMS High SES individuals	Independent Pharmacies Pharmacists Food industry / food production Businesses Fast-food industries (pepsi, coca cola, wendys, mcdonalds, etc) Transportation industry

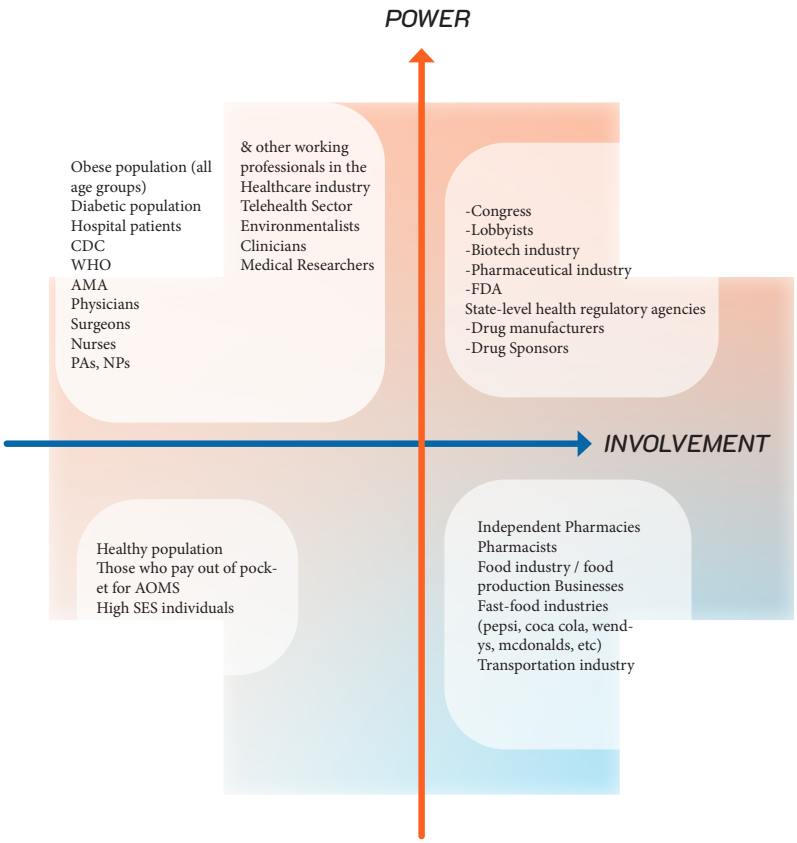

Figure 2. Actor Mapping: Involvement & Impact versus level of power in policy change

- **Low involvement & impact vs. Low power**: Individuals and groups who are not affected by obesogenic environments and/or suffer from chronic weight problems will likely be indifferent to legislative action.
- **High involvement & impact vs. Low Power**: This includes the target population of users, both current and future / those who would in general benefit from BMI reduction. The reason for the inclusion of the CDC, WHO, AMA, physicians, nurses, clinicians, etc., in this category is because of the power paradox between healthcare industry having minimal leverage on economic and political structures while simultaneously being held responsible for meeting the burden associated with health outcomes of obesity; the sector has minimal policy leverage over the determinants of such health outcomes. This paradox will be delineated in the power cube below
- **Low involvement & impact vs. High Power:** The commercial businesses and transportation systems of built environments have low involvement in public health policy yet sector lobbyists influence politicians in the high power quadrant above.
- **High involvement & impact vs. High Power:** The actors who possess high power and high impact / involvement collectively make up stakeholder groups within regulatory agencies. With that said, the responsibilities of regulatory agencies at the federal level have been mostly abdicated to individuals and the private sector. The notion that the obesity epidemic is not reversible without government action and investment is universally accepted in both literature and rhetoric.

The power cube can help elucidate the dynamic and dimensionality of interactions between actors of varying status. Power dynamics are important not only in the context of evaluation purposes but also for understanding the fundamental level of things. In other words, the structure of society, institutions and organizations / communities is not accidental, yet these intentional imbalances are not impossible to rectify. Finding a leverage point can help break through that gridlock of overlapping power interactions.

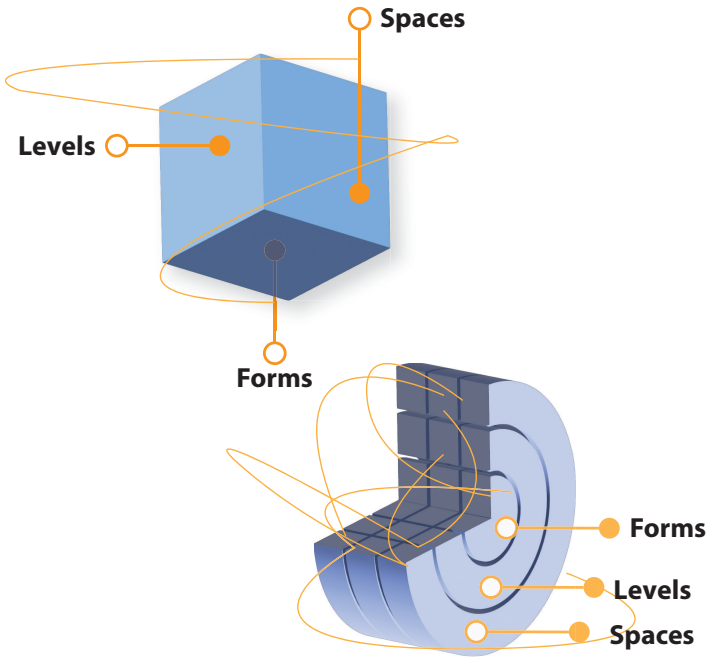

Figure 3. Power Cube

Dimensions: Depth

Forms of Power	Visible	Hidden	Invisible
Definition	This dimension includes formal institutions and decision-making processes that are overt and easily observable. It encompasses things like laws, regulations, policies, and official positions of authority.	This dimension involves control of information, or manipulation of norms and values. Hidden power can influence decision-making processes behind the scenes and shape the agenda in inconspicuous ways	Invisible power operates at the level of culture, ideology, and socialization, shaping what is considered normal or acceptable within a society or group. MAIN LEVERAGE POINT
Identified in Context of AOM Power Structure	Treat and Reduce Obesity Act 2023 FDA	Food production business and large companies that make up that monopoly	Obesogenic environments (created through business who profit off of people who overconsume)

Dimensions: Length

Places	Individual / micro	Local / Meso / state-level	National / Macro-Meso	Global / Macro / environmental
Definition: Levels of public and social life - where does the problem**?**			MAIN LEVERAGE POINT	
Identified in Context of AOM Power Structure	Internalized Intrinsic motivation	doctor's office, gyms, places like weight watchers,	Drug manufacturers such as Novo Nordisk Hospitals, tertiary sectors of the economy, such as	government policymakers and state regulatory agencies

Dimensions: Width

Spaces	Closed	Invited	Created / Claimed
Definition: Physical (or virtual) spaces where discussion and debate on the issue actually			MAIN LEVERAGE POINT
Identified in Context of AOM Power Structure	government meetings, sideline conversations between lobbyists, etc	educational programs, interventions to increase PA, preventive interventions by CDC	virtual spaces such as telehealth, online weight loss programs

Key takeaways from power cube

- Online weight loss platforms that prescribe AOMs (or get you started on the path to obtaining a prescription) are becoming more widely used, especially with the difficulty and cost of finding a PCP or NP. Some examples of these include Noom Med, Calibrate, Plenity, and Found. These companies apply to this evaluation because their theory of change models all begin with medication as the first line of defense against obesity. Their theories are rooted in obesity being a genetic and biological issue.

- The power that drug manufacturers currently hold is a major force at play. They hold knowledge. And that knowledge is in the form of a manufactured pill that has the potential to save lives and save the economy billions of dollars and save the environment from the impacts of overproduction.
- Giving individuals access to a medicine completely changes the dynamics of power between social, economic, and political forces that have hidden and invisible social control. However the government often sees bodily autonomy as a dangerous weapon

IV. Primary Stakeholder Platforms: Online Weight Loss Programs

Table 3. Comparing the features of two online weight loss programs

Categories	Calibrate	Plenity
Approach	Sustainable weight loss program based on biology; emphasis on medication first and lifestyle in addition	FDA-cleared weight loss device
Methodology	Focuses on the One-year metabolic reset that uses GLP-1s and behavioral therapy / lifestyle intervention	Drug- and stimulant-free capsules
Guarantee	Guarantees results	No explicit guarantee
Enrollment	Online quiz followed by lab tests and doctor consultation	Prescribed by doctors, also available through primary care physician
Support	One-on-one video chat with an accountability coach	Free, unlimited follow-up visits with telehealth doctor
Cost	Subscription to membership is $1650 for 52 weeks	Subscription cost of $98 for a four-week supply
Efficacy	Claim of at least 10% weight loss within a year or refund	Clinical trial results show participants generally lose 5% of body weight

Table 3. Comparing the approaches, methods, guarantees, enrollment processes, activities, costs, and efficiencies, of two online weight loss programs, Calibrate and Plenity.

Program #1: Calibrate

Calibrate is an online weight loss platform that promotes its core program, the Calibrate One-Year Metabolic Reset, which is backed by decades of clinical research and is brought to consumers directly through a virtual program. The program requires a year long commitment and includes an initial assessment by a doctor followed by tailored treatment using FDA-approved medication. Members work with an accountability coach through video chats and track their progress through the Calibrate App. The purpose-built app is where the bi-weekly video chats take place, as well as where they input their goals and track their progress. Tracking progress includes daily tracking of food, energy level, weight, and bi-weely goals The app also gives members access to resources like classes, recipes, and workouts, as well as ways for members to interact with other members of the Calibrate community.

Calibrate members receive AOM medications that belong to the GLP-1 receptor agonist family of drugs (i.e. Ozempic, Wegovy, Saxenda, etc.) as the first step of treating, maintaining, and preventing obesity. The inclusion criteria for Calibrate members includes being of ages 18 to 64 and having a BMI over 30. Membership approval is contingent upon individuals residency and health insurance status, as members must live in the U.S. and have health insurance. Calibrate's exclusion criteria includes those with active eating disorders, recent bariatric surgery, or with history of certain medical conditions. Calibrate measures and defines success as percent reductions in weight, waist circumference, and percent increases in blood sugar, inflammation, and cholesterol levels. Initial findings indicate that program success can be defined as having a 15% reduction in overall body weight.

Table 4: Calibrate Logic Model

Inputs	Activities	Primary Outcomes	Secondary Outcomes
Doctor Assessment	Bloodwork	Determine if medication is the right fit	**Guided tapering**
GLP-1 Medication	Take medication daily	**10-15 lbs reduction or 15% body weight**	Weight loss improves lifestyle routine
Intensive Behavioral Therapy / Intensive Lifestyle Intervention	Bi-weekly virtual sessions with coach; Goal setting and Goal checking	**New lifestyle routines**	
Time	52 week commitment	6 month outcomes	12 month outcomes
Cost			

Table 4. Calibrate's theory of change is based on its key product, the One-Year Metabolic Reset, which in combination with GLP-1s and IBT / ILT to meet the body's biological "set point." AOMs are not designed to be sustained through the whole year.

Program #2: Plenity

Plenity, an FDA-cleared weight loss aid, targets overweight or obese individuals by inducing a feeling of fullness, thereby reducing food intake. Unlike comprehensive lifestyle programs, Plenity strictly focuses on weight loss while advocating for exercise and healthier eating habits. The prescription-based weight loss aid, made from naturally-derived ingredients, is designed to swell in the stomach and is excreted without absorption by the body. Available to adults aged 22 and older with a BMI between 25 and 40. To initiate Plenity treatment, individuals can request a tele-health consultation with a licensed physician specializing in weight loss management. Clinical studies have shown promising results, with nearly 60% of participants achieving at least a 10% reduction in body weight observed within the first eight weeks of use. However, Plenity may not be suitable for individuals with a history of certain gastrointestinal conditions or allergies, and its long-term effects on weight maintenance and gut health remain under investigation. Known side effects include abdominal discomfort and bloating.

Table 5. Plenity logic model

Inputs	Activities	Primary Outcomes	Secondary Outcomes
Plenity Medication	Doctor consultation Pill is taken twice daily	8 weeks - % weight lost	New lifestyle routines Side effects
Cost	Four week cost: $98		

Table 5. Plenity is a four week program that focuses on weight management specifically

The company that makes and develops Plenity conducted its clinical study of the weight loss aid to determine its safety and efficacy and to get FDA approval. The company wanted to determine if at least 35% of participants lost 5% of their body weight within the six month period. The study had 436 participant who were overweight or obese, some of which had type 2 diabetes but the company did not specify how many. Over the 24-week-long study participants were randomly chosen to be given Plenity or a placebo. They were also instructed to exercise and reduce their calorie intake. The three main findings were that 59% of the Plenity group lost 10% or more of their body weight (an average of 22 pounds). Of this 59%, almost half (26%) lost 14% of their body weight on average (or approximately 30 pounds). Overall, the group who were randomly assigned Plenity over the placebo achieved more than 3% weight loss within the first 8 weeks.

Developing Key Evaluation Questions for Process Evaluation

Using each program's logic model and evidence from clinical studies, we are able to develop corresponding evaluation questions that will inform and guide our project. According to a guide published by the CDC on developing process evaluation questions, there are five central questions that should guide a process evaluation, each of which should provide the following information: "1) whether the program activities were accomplished, 2) quality of the program components, 3) how well program activities were implemented, 4) whether the target audience was reached, and 5) how external factors influenced program delivery" (CDC 2018).

V. Evaluation Project Design

Figure 4. Project logic model

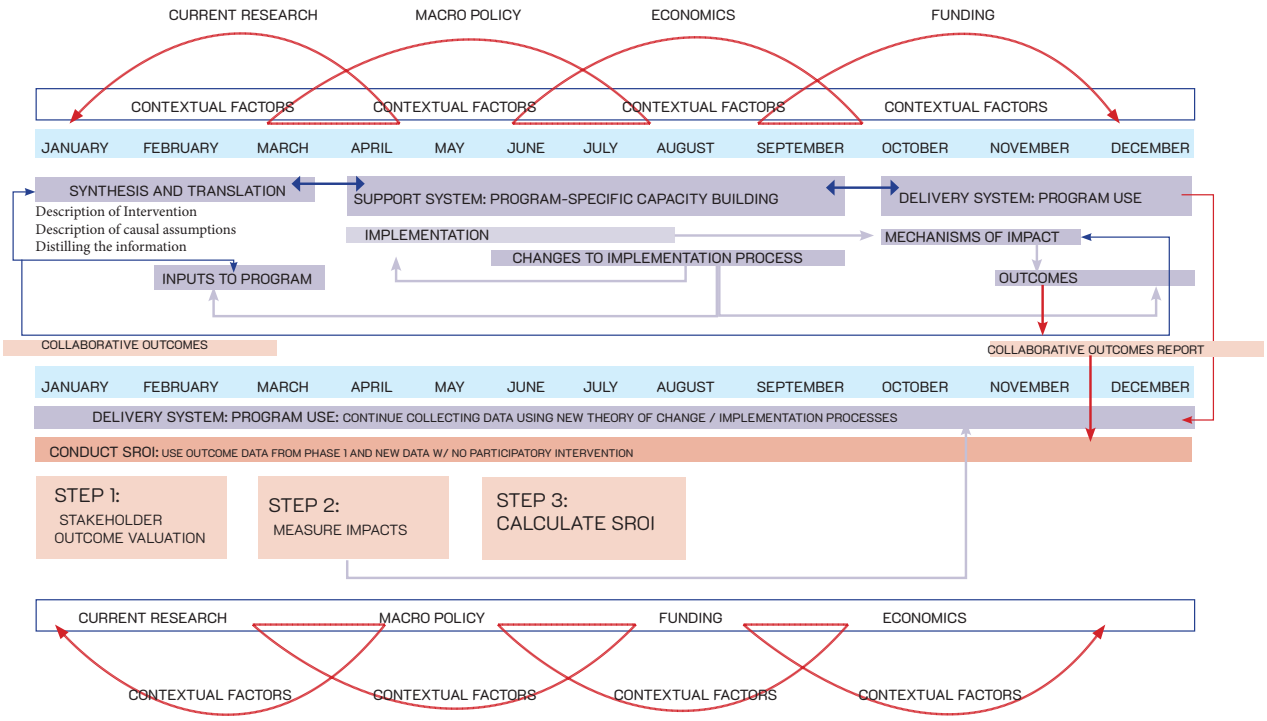

Table 4A. Data Collection Time Frame

	Jan 2025											**Dec 2025**
Calibrate data collection	X			O	O	XXO				O	O	XXX O
Plenity Data Collection	X	XX	X	XX	X	XXX	X	XX	X	XX	X	XXXX
	Jan 2026											**Dec 2026**
Calibrate data collection	X		O	O	O	XXO	O	O	O	O	O	XXXO
Plenity Data Collection	X	XX	X	XX	X	XXX	X	XX	X	XX	X	XXXX

- X = short term outcomes; XX = primary outcomes (i.e. weight loss as a percent) are recorded based on program's logic model; XXX = long-term outcomes visible and collected (per logic model); O = qualitative data collected through bi-weekly coaching meetings (which will be introduced during support system phase of ISF)
- Green / year 1: Process evaluation: Evaluation team has participatory influence with program leaders / sponsors / stakeholders (doctors, coaches, dietitians, etc.)
- Orange: Data collection continued during Phase 2 / SROI analysis, evaluation team no longer interacting with programs directly

Phase 1: Designing and Conducting a Process Evaluation Using an Interactive Systems Framework for Dissemination and Implementation Approach and a Collaborative Outcomes Reporting Method for Data Collection and Analysis

The purpose of incorporating the Interactive Systems Framework for Dissemination and Implementation (ISF) into the design of Phase 1 is because the ISF approach allows us to actively bridge the gap between research and practice in a way that is policy-change oriented. This framework has three non-linear systems / phases that are meant to build off of each other in an iterative fashion.

Table 6. Interactive Systems Framework for Dissemination and Implementation

System	The Prevention Synthesis and Translation System	The Prevention Support System	The Prevention Delivery System
Activities	Distill information about innovations; Translate information into user-friendly formats	Provide training, technical assistance, or other support to users in the field	Implementation of prevention programs and other innovative tactics / strategies
Purpose / role in our evaluation design	The dissemination of knowledge and usability is important in the context of how evaluation works to serve the greater good of the public	This sub-phase will allow us to support new forms of data collection, particularly the collection of qualitative data	The implementation of these programs can be understood as a facet of healthcare service delivery.

The ISF was developed by researchers in the article, *Bridging the Gap Between Prevention Research and Practice: The Interactive Systems Framework for Dissemination and Implementation (*2008). According to the authors, each of the three systems of activities are crucial for successful dissemination and implementation of prevention programs in practice: "This framework is intended to be a heuristic framework for organizing the theory, research, and practice (activities) of the dissemination/ implementation process … [T]he three systems should optimally work together for successful dissemination and implementation of prevention innovations" (Wandersman et al., 2008). The framework was developed with the intent of being utilized by stakeholders who could use it to better see prevention systems through different perspectives in order to better understand the needs of other stakeholders and systems.

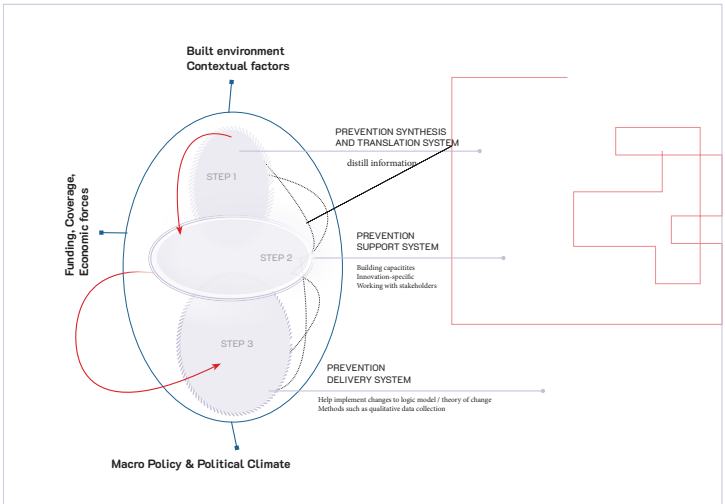

Figure 5. Interactive Systems Framework

The three systems will be implemented in tandem with the six steps comprising Collaborative Outcomes Reporting (COR). According to Better Evaluation[1], COR "is a participatory approach to impact evaluation based around a performance story that presents evidence of how a program has contributed to outcomes and impacts, that is then reviewed by both technical experts and program stakeholders, which may include community members" (Dart, 2021).

[1] https://www.betterevaluation.org/methods-approaches/approaches/collaborative-outcomes-reporting

Table 7. Collaborative Outcomes Reporting: Six Steps for Data Collection and Analysis

Step Name	Step Description	Main Activities
1. Scoping	The scope of the program is identified	An inception workshop or planning workshop is held with program leaders
2. Data Trawl	Primary and secondary data sources are made transparent	Existing evidence that supports each program's logic model or theory of change is discussed amongst stakeholders
3. Social Inquiry	Data gathering	The programs are carried out and data is collected through its normative process
4. Data Analysis and Integration	Quantitative and qualitative data can be analyzed together according to the outcomes in the program's logic model	A results chart is used to integrate different sets of data
5. Outcomes Panel	External and internal stakeholders are brought together	People with relevant knowledge or expertise are brought together to discuss outcomes seen in the results chart from step 4
6. Summit Workshop	Key findings and recommendations are synthesized	Iterative process that will go on into Phase 2 of our evaluation plan

Table 7. The steps and main activities are developed from the COR guide from the Better Evaluation website (https://www.betterevaluation.org/methods-approaches/approaches/collaborative-outcomes-reporting)

Phase 2: Conducting a Social Return on Investment Analysis

Phase 2 entails conducting an SROI analysis. The main difference between SROI and the COR approach used in Phase 1 is that the SROI will give financial value to various stakeholder outcomes (rather than just looking at the program outcomes in terms of program sponsors and stakeholders). The rationale for utilizing an SROI in combination with the process evaluation and COR approach stems from the prevailing need of economic evaluations for obesity prevention efforts.

According to the article, *Economic Evaluations of System-Based Interventions - The Case for a New Approach (2018)* it is more effective for policy change purposes to evaluate system-based interventions or prevention systems using "methods of performance measurement commonly applied in health sciences, public health, and economics, such as comparing an intervention's return-on-investment with its opportunity costs … such assessments of performance measurement could be more useful in political decision making processes that the well-established criterion of cost-effectiveness. This is particularly true for those processes in which affordability and 'non-economic' criteria like alignment with government policy are relevant" (Sonntag et al., 2018). In short, including multiple stakeholder perspectives through an SROI allows for the evaluation team to make sound judgements on how investments will impact the health trajectories and social well-being of the obese population.

Overall, there are seven key principles within an SROI analysis: involve stakeholders, understand what changes, value what matters, only include what is material, do not over-claim, be transparent, and

verify the result. These principles hold true throughout each of the six stages of the SROI process, each of which has a number of activities that build upon one another.

Table 8. Social Return on Investment: Stages and Activities

	Description	Activities
Stage 1	Establishing Scope and identifying stakeholders	1.1 Establish scope 1.2 Identify stakeholders 1.3 Decide how to involve stakeholders
Stage 2	Mapping outcomes	2.1 Start the impact map 2.2 Identify inputs 2.3 Valuing inputs 2.4 Clarify outputs 2.5 Describe outcomes
Stage 3	Evidencing outcomes and giving them value	3.1 Developing outcome indicators 3.2 Collecting outcomes data 3.3 Establishing how long outcomes last 3.4 Placing a value on the outcome
Stage 4	Establishing impact	4.1 Deadweight and displacement 4.2 Attribution 4.3 Drop-off 4.4 Calculate impact
Stage 5	Calculating the SROI	5.1 Projecting 5.2 Calculate net-present value 5.3 Calculate the ratio 5.4 Sensitivity analysis 5.5 Payback period
Stage 6	Reporting, using, and embedding	6.1 Reporting to stakeholders 6.2 Using the results 6.3 Assurance

An SROI is an outcomes-based measurement tool. Indicators are applied to outcomes as measures of change. Together, the two denote impact for each stakeholder. For the purposes of this proposal, we will highlight stages 1 through 3 in alignment with our proposed logic model.

Stage 1: Establishing Scope and Identifying Stakeholders

Data collection will continue from the two online weight loss platforms, but the stakeholders from these programs will not be physically present at the SROI. Program sponsors are not included in the collaborative meetings between stakeholders (part of stage 1 of the SROI) in order to give Phase 2 – and the overall project – more of a public-interest stance towards obesity prevention and policy change: “if the sponsors of programs (i.e. Calibrate and Plenity team members) control the evaluations and evaluators,

they may well design evaluations to further their own self-interests rather than provide unbiased information for the public interest" (Datta 2011).

Table 9. Stage 1 of SROI: Stakeholder Involvement, Rationale, & Desired Outcome

Stakeholder	Reason for Inclusion	Outcome
Intended users / affected population	Main users	Weight loss; improved cardiovascular health; reduction in likelihood of diabetes
Congressional Budget Office	Inform policymakers	Empirical evidence of cost-effectiveness
Federal Insurance Programs / Medicaid and Medicare officials	Involved in deciding policy / enacting policy	reduced spending on unnecessary or unanticipated health outcomes
Policymakers / congressmen	Decision makers	Budgetary gains long-term
Private insurance companies	Influenced by policy change	Price of drugs (supply and demand)
Lobbyists who support theTreat and Reduce Obesity Act	Money = power	Outcomes associated with AOM efficacy
Primary care physicians	Most people who use online weight loss programs need to see one for a consultation	They could be observing actual results from baseline
Drug Manufacturing Companies (ex: Novo Nordisk)	They manufacture the GLP-1s	Effectiveness in managing obesity
FDA Director	director of the Division of Diabetes, Lipid Disorders, and Obesity in the FDA's Center for Drug Evaluation and Research	Cross comparison between obesity and diabetes prevalence
Labor Union leaders	Give first-hand information and accounts about lost productivity in the job	Productivity increases
Pharmaceutical companies - executives / researchers	Major third party involved in production and supply for implementation	Financial gain / losses from policy change that would subsidize prescriptions
CDC (diabetes sector) lead researchers for their two national diabetes prevention programs	Major areas of preventative health measures	Similar outcomes are in alignment with preventative health practices
KFF (health policy research non-profit)	Knowledge and expertise	Replication of findings
USC faculty in the health policy and economists school	Knowledge and expertise; Economic policy of public health initiatives	Replication of findings
Pharmacists	the main third party involved for drug implementation	Or less issues with filling these prescriptions due to shortages
heart surgeons; Surgeons, lab technicians, highly skilled nurses	Doctors who deal with the burden of rising obesity; more incidence of heart attacks	Reduced incidence / hospitalization

Stage 2: Mapping outcomes

Outcome mapping is a useful technique in evaluation, particularly because it allows for the systems approach to be readdressed by focusing on outcomes in different sectors while collectively defining them through a financial descriptor / economic valuation.

VI. Reporting and Data Analysis

Phase 1: Outcome Reports

The Process Evaluation conducted in Phase 1 follows a Collaborative Outcomes Reporting (COR) Methodology. Outcome reports are also referred to as "Performance Story Reports" and are typified by being short in nature while also delineating key aspects of the program. More specifically, these short reports highlight how a program contributed specifically to the outcomes seen in participants or users by drawing upon the causal relationships theorized in their logic models. The reports are specific to program context, its goals, are related to a plausible results chain, and utilize empirical evidence.

The Performance Story Report technique used in this evaluation project is known as Participatory Performance Story Reporting (PPSR).[2] This technique is characterized by five elements which align with the six steps of the COR method (Table 9). The five-part structure ultimately aims to explore and report the extent of causal relationships between the programs inputs and activities and its outcomes.

Table 10. Participatory Performance Story Reporting (PPSR Technique) for the COR Method

COR Step Name	Main Activities	PPSR Reporting: Section and Main Activities
1. Scoping	An inception workshop or planning workshop is held with program leaders. The scope of the program is identified	A narrative section explaining the program context and rationale
2. Data Trawl	Existing evidence that supports each program's logic model or theory of change is discussed amongst stakeholders. Primary and secondary data sources are made transparent	A narrative section describing the implications of the results (both expected and unexpected) as well as the issues and the recommendations
3. Social Inquiry	Data gathering. The programs are carried out and data is collected through its normative process	Narrative section that provides a number of first-person narrative accounts of significant change; this is done through incorporating qualitative data collection processes

[2] https://www.betterevaluation.org/sites/default/files/report-on-outcomes-and-get-everyone-involved_the-participatory-performance_0.pdf

COR Step Name	Main Activities	PPSR Reporting: Section and Main Activities
4. Data Analysis and Integration	Quantitative and qualitative data can be analyzed together according to the outcomes in the program's logic model. A results chart is used to integrate different sets of data	A results chart that summarizes the achievements of a program (intended outcomes, goals met, unintended outcomes)
5. Outcomes Panel	External and internal stakeholders are brought together to discuss outcomes seen in the results chart from step 4	An index that provides more detail on the sources of evidence

Table 9. How COR reports are built throughout Phase 1.

Results Charts

Reports will be published for both program process evaluations using the results charts and the narrative accounts from both program sponsors and program users (i.e. participants). A major aspect of collaborative outcomes reporting through a PPSR framework is that the results charts allow for distinctions to be made on the actual contribution of a program and its actual attribution to empiric evidence and knowledge sources. The outcomes that are recorded in the results charts for both programs should directly inform the outcomes that are inserted into the SROI analysis table.

Table 11. Calibrate Results Chart

Goals (from logic model)	Intended Outcomes (from logic model)	Goals met?	Outcomes met?	Unintended outcomes
Weight loss Metabolic Reset	10-15% reduction in body weight	Blood sugar levels stabilized	Reduction in waist circumference	How long did they stay on the medication in order to reach desired set point
Lifestyle changes - ex: better sleep	Lifestyle factors help reduce and maintain reduced weight	Better sleep is a goal	Weight loss is an outcome	Did better lifestyle habits alter weight loss or did the GLP-1 drugs?

Table 12. Plenity Results Chart

Goals (from logic model)	Intended Outcomes (from logic model)	Goals met?	Outcomes met?	Unintended outcomes
Reduction in BMI	10% reduction in body weight	What proportion of participants had reductions in BMI?	What proportion reduced 10% or more of their total body weight	- Side effects - Unanticipated lifestyle changes

To illustrate how the results chart can be utilized for demonstrating causal pathways between the program and the outcome, methodological steps need to be taken in order to reduce error made possible by confounds such as self-report bias or non-response bias.

Phase 2: SROI Reporting and Analysis

One type of evidence that the CBO has examined comes from simulation models used to estimate the amount of spending on AOMs that would eventually be offset by reductions in healthcare spending. However, the results are mixed; one study published by New England's Comparative Effectiveness Public Advisory Council found that individual spending on AOMs actually increased overall health care spending.[3] Similarly, the same study found that, compared with lifestyle changes, using AOMs also increased healthcare spending at the individual level; estimated reductions in non-drug spending found that only amounted to about one-fifth the cost of the drug.

Another study conducted by the University of Southern California found that AOMs did result in increased savings in the health insurance sector, yet the study did not incorporate direct cost of the medication. Therefore, it is crucial that medication cost be incorporated into the SROI so that results can demonstrate return-on-investment for the federal budget. Overall, the reporting and analysis of the SROI needs to focus on incorporating outcomes and indicators for participants and intended users as well in order to understand if their high cost up front is truly more beneficial long-term.

Table 13. Giving Stakeholder Outcome's Indicators for Measurement

Stakeholder	Outcome	Indicator
Intended users of AOM medication	Weight loss	% lost in inches of total body weight; inches lost on waist circumference
Labor union	Increased productivity on the job	Less sick days; more hours worked

[3] Medications for Obesity Management: Effectiveness and Value. https://icer.org/wp-content/uploads/2022/03/ICER_Obesity_Final_Evidence_Report_and_Meeting_Summary_102022.pdf. 2022.

Stakeholder	Outcome	Indicator
Policymakers	Long-term financial benefit	Less money spent on healthcare sector for unanticipated hospitalizations

Stage 3: Evidencing outcomes and giving them value

A key activity in this stage will be establishing how long outcomes last. This will be a significant outcome that is important to stakeholders who are deciding whether or not there is investment value in AOMs.

Table 14. Giving Outcome Indicators Value

Outcome	Indicator	Value
Weight loss	% lost in inches of total body weight; inches lost on waist circumference	(Insert price of AOM per week or month, just keep consistent
Increased productivity on the job	Less sick days taken by employees	Increased GDP in labor
Long-term financial benefit	Less money spent on health care sector for unanticipated hospitalizations	Average cost of hospitalization due to heart attack or stroke ($/day) is put back into budget

Stage 4: Establishing Impact

This stage underscores the significance of systems-based approaches in evaluating the administration, implementation, impact, and long-term effects of AOMs, utilizing both health performance data and return-on-investment analysis methods. Even in the nascent stages of AOM utilization via online medical weight loss platforms, it is imperative for our evaluation team to explore potential impacts in response to macro-level weight loss:

a. **Politics & Policymaking:** Federal medical care and private insurers alike do not currently have policies allowing them to subsidize coverage for prescription medications that prevent / manage obesity specifically. Congress has advocated for The Treat and Reduce Obesity Act 2023 which would change that policy. The CBO wants to understand the implications of population-level weight loss.
b. **Economics:** How will changes in consumer habits affect the industrial economy, including agriculture and food production and consumption?
c. **Environment:** What will be the ramifications of a reduced percentage of overweight individuals on energy and fossil fuel consumption?
d. **Built Environment:** Will societies become more urbanized and conducive to walking or biking if more individuals are physically fit to do so?
e. **Healthcare:** How will healthcare systems reallocate funds if less money is spent on unanticipated hospitalizations?

Stage 5 & Stage 6: Calculating the SROI & Reporting, Using, and Embedding: As stated in the CBO's call for research on AOMs, useful research would be focused on "factors influencing AOM use, patient adherence, pricing, and long-term clinical impacts is essential. This research would inform analyses by entities like the CBO and assist policymakers in making evidence-based decisions regarding Medicare coverage of AOMs" (Swagel, 2023).

VI. Expected Outcomes and Implications of Findings

As outlined in the executive summary, the expected outcomes were: 1) To enhance the capabilities (efficacy, effectiveness, scope) of online medical weight loss programs (namely, Calibrate and Plenity) to improve accessibility to healthcare services, and 2) to produce a collaborative outcome report and SROI reports that incorporate stakeholder perspectives and empirical evidence that will hopefully influence policymakers, insurers, and the private sector to make policy coverage changes that will subsidize GLP-1s as AOMs as a method of preventive healthcare. Existing evidence suggests that the cost of AOMs may outweigh the savings in healthcare costs, potentially leading to a net increase in the deficit over the next decade. However, this outlook could evolve depending on factors such as AOM prices and their longer-term effects on healthcare utilization. Evidence on the cost-effectiveness of AOMs presents a mixed picture, with some studies suggesting potential savings in healthcare costs while others indicate that AOM use might increase overall healthcare spending, particularly in the short term.

VII. Project Limitations to Sustainability

Conducting a comprehensive evaluation is imperative to assess the feasibility, implications, and potential strategies for implementing changes to Medicare regulations concerning obesity drug coverage. Balancing the need to address rising obesity rates among beneficiaries with the financial implications of reimbursing costly medications presents a significant challenge to this evaluation. Moreover, the diverse opinions among stakeholders, ranging from patient advocacy groups to pharmaceutical companies, insurers, and policymakers, further complicate the formulation of effective and sustainable solutions. Lastly, the uncertain long-term cost-saving benefits, coupled with existing healthcare system constraints – such as high attrition rates and potential adverse effects on healthcare costs – underscores the complexity of the issue.