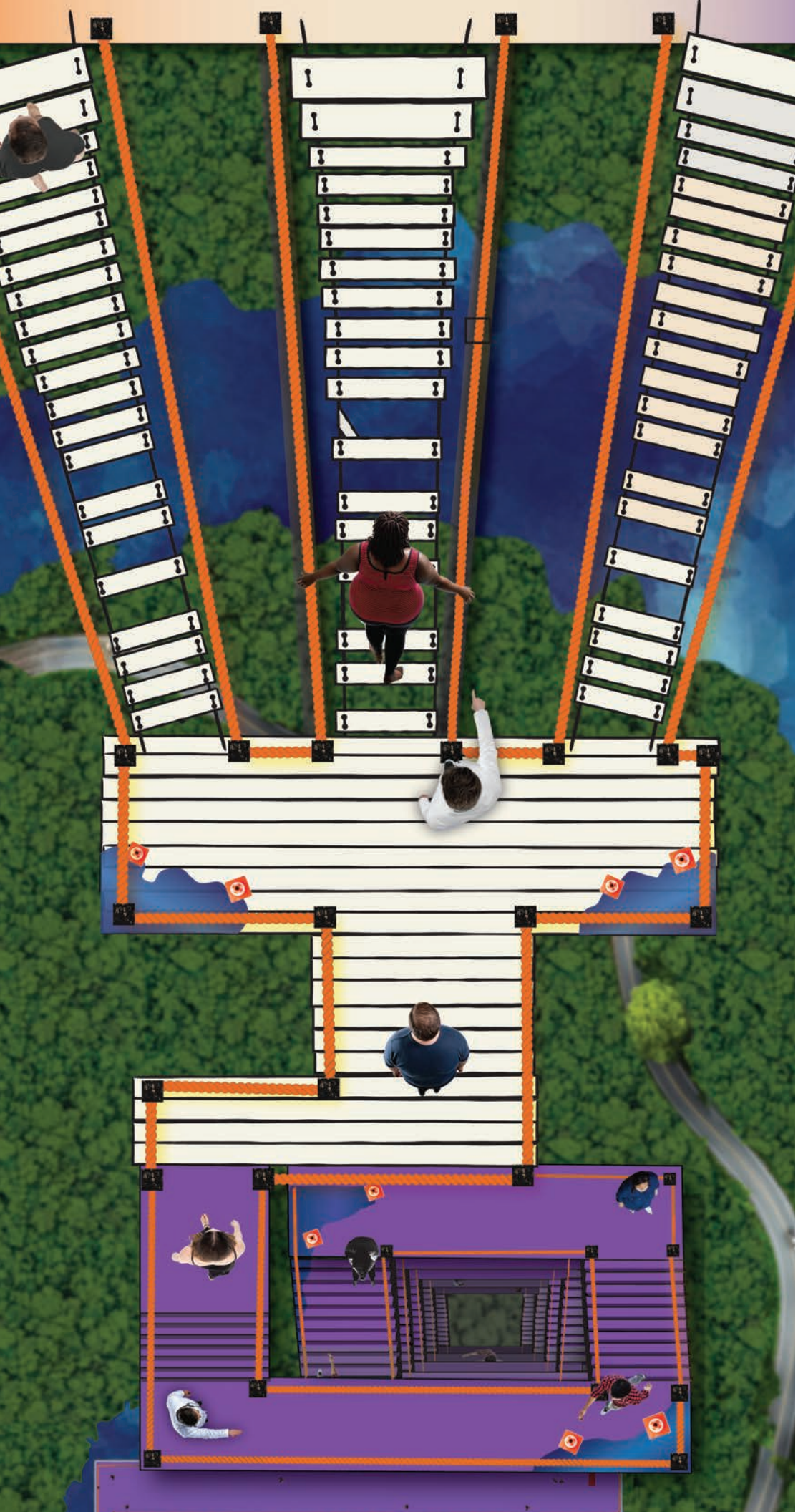


CBSD
Center for Biomedical System Design

A roadmap for transforming obesity disease management

June 2025

TuftsMedicine
Tufts Medical Center

EXECUTIVE SUMMARY

A roadmap for transforming obesity disease management

The United States faces a full-blown health epidemic of obesity that we are slowly shifting to better manage. Medical and technological advancements have provided us with a unique opportunity to holistically address this health epidemic. To fully embrace opportunities to treat patients and reverse obesity rates, system-level, integrated shifts must occur simultaneously. Working together, we can build a system of medical care for obesity that works for all those affected by this disease and provides a roadmap for how all stakeholders in healthcare can contribute to population health-level challenges.

The NEWDIGS consortium in the Center for Biomedical System Design (CBSD) at Tufts Medical Center is dedicated to improving patient outcomes through improved equitable access to biomedical innovations, in ways that work for all stakeholders. CBSD takes a systems approach to designing, evaluating, and catalyzing important advancements whose complex and cross-cutting nature are such that they cannot be addressed by a single organization or market sector. The CBSD Obesity Medicines Project has been working since early 2024 to improve US health systems' readiness to treat obesity as a disease by articulating system-wide challenges in obesity care and designing and pressure testing comprehensive solutions for the care of patients with obesity.

This Roadmap for Transforming Obesity Disease Management presents the results of the multi-stakeholder, cross-functional consortium which identified 36 action components under ten solution elements grouped within three key solution areas that help to codify the changes that must occur if we are going to be prepared to support the epidemic of obesity. The Roadmap relies on specific key assumptions:

- That the future-state obesity healthcare system is possible to attain within 3-5 years;
- That parallel efforts will achieve coverage by most payers, including Medicare and Medicaid, for modern obesity medications and ancillary services within this 3-5 year timeframe;[1] and
- That product shortages will be alleviated thanks to expanded manufacturing capacity and additional market entrants.

With this work, we pressure-tested whether this approach would create a proactive, learning system that provides comprehensive support for patients, trains healthcare providers, encourages adequate and standardized coverage for obesity care (i.e., not just weight loss), and is sustainable for all stakeholders involved.

Solution Area 1: Patient Identification, Engagement & Diagnosis

First, Healthcare providers must be able to **identify, diagnose, and treat** people with obesity such that the person feels confident that if they engage in the healthcare system, they will be treated respectfully as patients.

Rather than meeting patients with bias or stigma, Health Care Professionals (HCPs) and society at large must redress obesity, fully recognizing it as a chronic, heterogeneous disease that requires complex treatment. HCPs must have comprehensive, up-to-date evidence-based knowledge if they are to deliver care for people with obesity. Medical training at all levels and across a wide array of healthcare professionals must build knowledge of obesity standards of care, from screening and diagnosis to treatment options and reimbursement protocols. It must be normative behavior to reach patients with obesity and encourage them to enter care. People with obesity must believe that HCPs will treat them with respect and provide health solutions that will bring positive results that meet their needs. For people to engage as patients, Health Care Professionals (HCPs) must not operate with biased attitudes, and they must be able to offer treatments to patients once diagnosed.

Solution Area 1 Elements: Patient Identification, Engagement & Diagnosis, includes the following solution elements:

- Creating a comprehensive communication plan that reaches all society, eradicating bias and stigmas about people with obesity
- Educating healthcare professionals about the disease of obesity and its treatment from professional school curricula through to mandatory continuing education programs
- Normalizing patient outreach for medical treatment (and build confidence in patients that medical treatment will help)

Solution Area 2: Shared Capability Building

Second, the infrastructure to support a comprehensive obesity care process must be prepared to shift regularly. For example, as our understanding of the disease develops, coding and quality measures must be updated and developed so that we can measure what is working for patients and what may not. With this metrics infrastructure regularly improving, payers and providers will respond to rewards or penalties that recognize best practices for patients' desired outcomes. Moreover, stakeholders across the system must **share knowledge and capabilities** so that evidence can be available to change what care is provided, and influence how that care might be provided. By aligning incentives across the system, stakeholders can find ways to investigate best practices in real-world settings, establishing contracts that benefit patients while also building (and sharing) new evidence about what care pathways prove most effective. Through joint contracting, best practices can be established not only in care pathways, but in terms of what is best to measure. Do health outcomes improve if patient engagement is high from the beginning? Do rural subpopulations improve persistence if telemedicine services are provided? Do patients with obesity-related diseases sustain improvements if obesity is the main disease diagnosed and reimbursed? With so many unanswered questions, aligning incentives to establish investigatory contracts while tracking results will be a vital infrastructure improvement.

Solution Area 2 Elements: Shared Capability Building, includes the following solution elements:

- Regular updates of coding metrics that identify the disease and trigger reimbursement processes

- Quality measures and outcomes monitoring processes that nudge healthcare systems to reward effective and equitable care for people with obesity
- Comprehensive data collection and evidence generation that is shared to influence the care pathways for obesity care
- Align incentives and payments across healthcare stakeholders to deliver evidence-based obesity care programs that reward constantly improving standards of care and health outcomes to match

Solution Area 3: Integrated Care

Finally, **integrated care** will be possible for patients who need it. With data generated and research conducted, validated treatments, including ancillary services and medical treatments, can be offered to patients. These services will be utilized along care pathways that have been developed following medical standards of care. These evidence-based care pathways will continue to contribute to our knowledge base, as data is researched and shared.

Significantly, engaged patients will be ready to work with HCPs as they jointly navigate these new opportunities. Shared decision-making is a challenging concept: people with obesity today still struggle with the stigma associated with their own condition, undermining the knowledge they have about how to effectively treat their own condition. Yet, customized delivery will require that patients find their voice and advocate for care that is customized to their disease, local resources, and life conditions. Such a sea change will only be possible if the health care systems, key stakeholders, and the infrastructure to support such changes are in place, limiting (if not eliminating) the barriers to healthcare access that patients will need to find their voice and use it.

Solution Area 3 elements: Integrated Care, including the following solution elements:

- A set of treatments that have been validated through shared evidence and standards of care. These **validated treatments** will be updated regularly, as more evidence develops to track ancillary services that provide ongoing relief for this chronic disease.
- **Care Pathways** that evolve over time, as evidence is actively accumulated to build and share knowledge of successful, standards of care in the care of obesity
- **Delivery services that are customized** to best align with patient needs, considering a patient's level of knowledge, readiness for treatment, and personal preferences. Patients will also have access constraints due to socio-economic circumstances, geography, and/or health conditions (Customized Delivery).

Figure 1 depicts the multi-faceted and coordinated changes that will be required to effect transformation for most people living with obesity. The solution components within each solution area are summarized in Table 4 - Table 6 of the 'Obesity Roadmap Architecture: Solution Areas, Elements and Action Components' section of the paper. These Tables outline a significant amount of work that requires multiple stakeholders, working together.

No one solution area can bring about change on its own, but each solution area – from **patient engagement, identification and diagnosis**, to **shared capability building**, to **integrated care**—will be structures that support and strengthen one another to enable us all to transform obesity disease management.

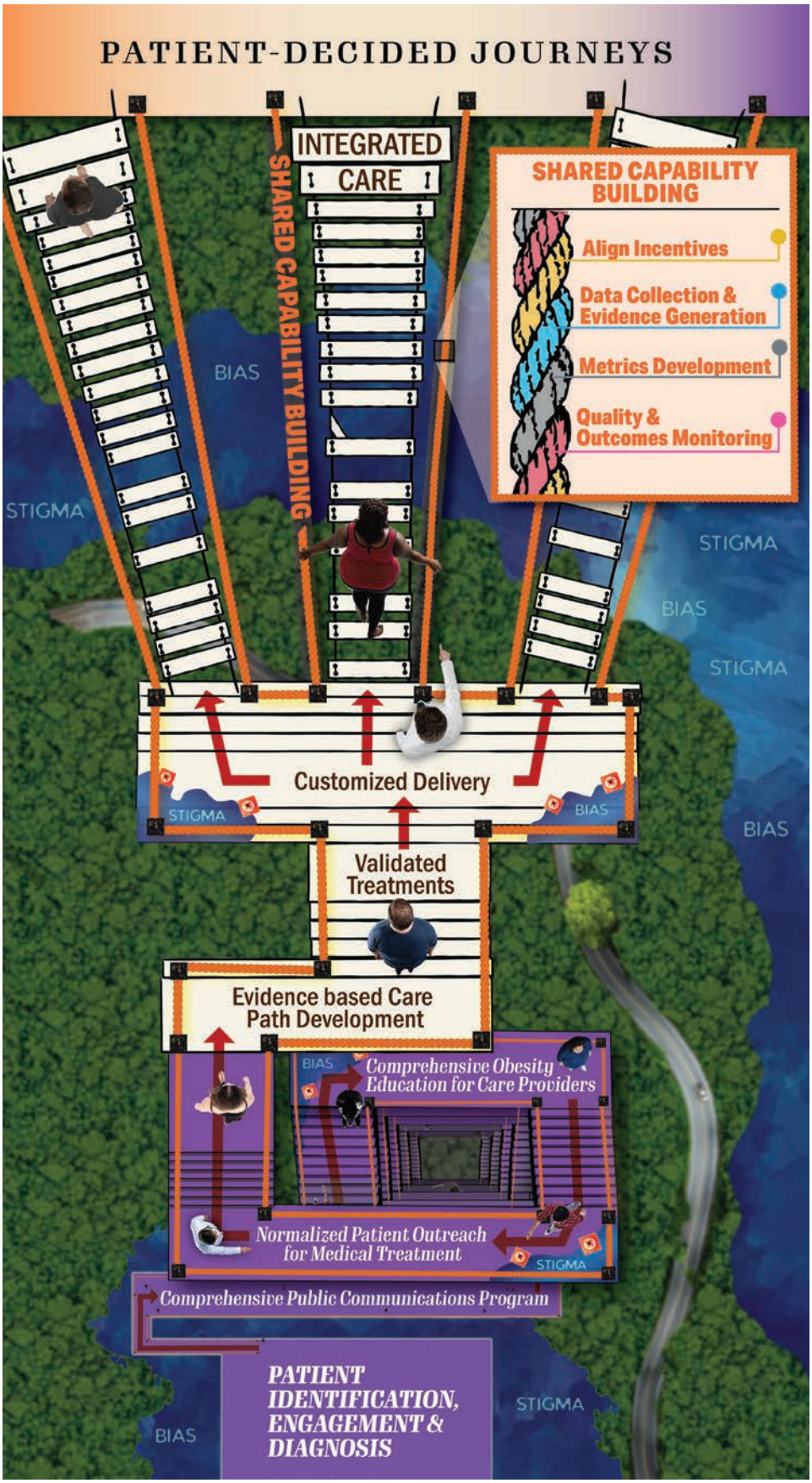


Figure 1: A Roadmap for transforming obesity disease management

Patient Identification, Engagement and Diagnosis (Purple staircase) is a challenging climb for patients, providers and payers to proactively address this chronic disease with medical treatment.

Bias & stigma (blue swamp) must be waded through by both patients and providers to start engagement – many do not succeed today.

Shared Capability Building (orange rope): Represented here as an inter-twined ropes and railings that support the other two solution areas through metrics, data collection, evidence generation, and aligned stakeholder incentives that reward best practices for achieving patients' desired outcomes. These form a rope handrail that provides structural support and handrails for all to grasp. These capabilities regularly up-dated, create continuous science-based improvement in an established **learning environment**.

Integrated Care (Tan platform & bridges): Where patients have multiple care pathways offering validated treat-ments from which to select through shared decision-making with providers and customized in their delivery to reflect the patient context and **Capaci-ty challenges** (represented by missing boards in the bridge).

Background

This Roadmap is the culmination of an 18-month effort by the multi-stakeholder NEWDIGS consortium in the Center for Biomedical Design at Tufts Medical Center. The process involved multiple working teams punctuated by all-stakeholder gatherings (Design Labs) every six months. Through this process, we endeavored to elucidate the challenges patients with obesity face, despite advances in obesity care and management, recognizing and clarifying access and outcomes impediments that impact patient care.[2] We also sought to articulate the design of a 3-5 year future-state obesity healthcare system that would encompass a proactive, learning system that provides comprehensive support for patients, trains healthcare providers, encourages adequate and standardized coverage for obesity care (i.e., not just weight loss), and is sustainable for all stakeholders involved.

To reach that future state, the consortium determined that a learning system in obesity care would require certain key conditions to progress early in the care transformation, including:

- We assume that the future-state obesity healthcare system is possible to attain within 3-5 years
- We assume that modern obesity medications will be covered in our timeframe by most payers, including Medicare and Medicaid
- We also assumed that product shortages will be alleviated thanks to expanded manufacturing capacity and additional market entrants[3]

Identifying solution elements for further investigation across three solutions areas, we endeavored to a) investigate these solution elements more thoroughly; b) articulate a set of recommended actions needed to effect change; and c) outline a roadmap that provides an integrative conceptualization of the challenges and solutions in establishing comprehensive care systems for people with obesity.

In each of the progressions of this work, the Center for Biomedical System Design (CBSD) works as a "think and do tank" dedicated to improving patient outcomes through improved equitable access to biomedical innovations, in ways that work for all stakeholders. CBSD takes a systems approach to designing, evaluating and catalyzing important advancements whose complex and cross-cutting nature are such that they cannot be addressed by a single organization or market sector. The CBSD Obesity Medicines Project has been working since early 2024 to articulate system-wide challenges in obesity care and to design and pressure test comprehensive solutions for the care of patients with obesity. This Roadmap for Transforming Obesity Disease Management is the culmination of this 18-month multi-stakeholder consortium involving connected working teams and three all-stakeholder Design Lab events.

Multi-faceted systems changes emerging from challenges

Through the consortium's iterative design process, the April 2025 Design Lab participants concluded that there are three solution areas where changes will, in combination, support a robust, proactive and effective health care response to the disease of obesity.[4] They refined the three solution areas, to create this Roadmap to transform our healthcare systems to respond to the broad array of obesity patients' needs.

First, **how patients are identified, engaged, and diagnosed** must be transformed. This initial stage is particularly impacted by stigma and biased perceptions of people with obesity across society and our healthcare systems.[5] From a medical perspective, as we shift from assuming obesity is a "lifestyle choice" to obesity recognized as a disease, health systems must accept the medical necessity of obesity treatment.

Second, new **shared capabilities** will require enhancement or creation of healthcare infrastructure to prepare for the necessary depth and breadth of obesity treatment. With a through-line of aligned incentives, shared capabilities must support improvements in coding, quality metrics, and clinical guidelines/standards of care in a timely manner. More than time sensitivity, there will be a toolbox of codes and metrics which will have to be used for different purposes, from diagnosis, to monitoring progress, to measuring a patient's level of risk and even determining access to levels of care. Currently, these metrics link back only to BMI, but the evidence-based taxonomy of metrics will shift to capture a more nuanced interpretation of this heterogeneous disease. With this more comprehensive articulation/ documentation of disease, the transparency of data generation, analytic skills, and real-world evidence generation will enhance our knowledge of what care pathways are most effective. With shared, ongoing, evidence-based learning, these capabilities will allow for care to be transformed. Shared capabilities that change systems will build confidence in the quality of care our healthcare systems can provide.

Working in tandem with the above transformations, our third solution area focuses on how patients and patient outcomes are best served by **integrated care**: based on the patient's more nuanced obesity and health status assessment, integrated care would include what care elements are offered, at what intensity, at what time, and customized to the patient's particular circumstances. We assume that the care delivery structures must expand in their capacity to treat patients, covering patients at varying levels of disease and offering different opportunities to receive care. Patients will engage more systematically as access to integrated care improves and patients have flexibility to customize the care elements to their specific circumstances. Integrated care practices must ensure that the care delivered maintains high quality across all treatment venues.

These three solution areas do not operate separately, but must be implemented in an integrative process, to generate the most inclusive and appropriate care for patients with obesity. A **patient's engagement** will improve as the care provided remains current and divorced from biased attitudes, and the systems work smoothly across each step of the care journey (**shared capabilities**). As patients are more trustingly engaged and shared capabilities ensure positive health systems responses are in place, **integrated care** systems will support flexible, varied, care delivery opportunities that share the basic understanding of obesity as a disease. Such multi-faceted systems changes will spark an upward positive cycle, where obesity care can be consistently revised, as new evidence shows what works best for patients with obesity.

In addition to these three solution areas, three pervasive systems-wide barriers (stigma and bias, learning impediments, capacity constraints) impact how obesity healthcare systems will develop and take hold. First and foremost, bias and stigma remain pervasive limitations to effective and efficient patient engagement and ultimately, care provision. Second, there is a pervasive need for more evidence-based, continuous learning coupled to comprehensive education for all stakeholders in the healthcare system. Finally, health care systems capacity remains a pervasive, fundamental systems-wide barrier to our ability to embrace obesity care. These three systems-wide barriers must be overcome uniformly so that we can ensure that health systems are ready to address

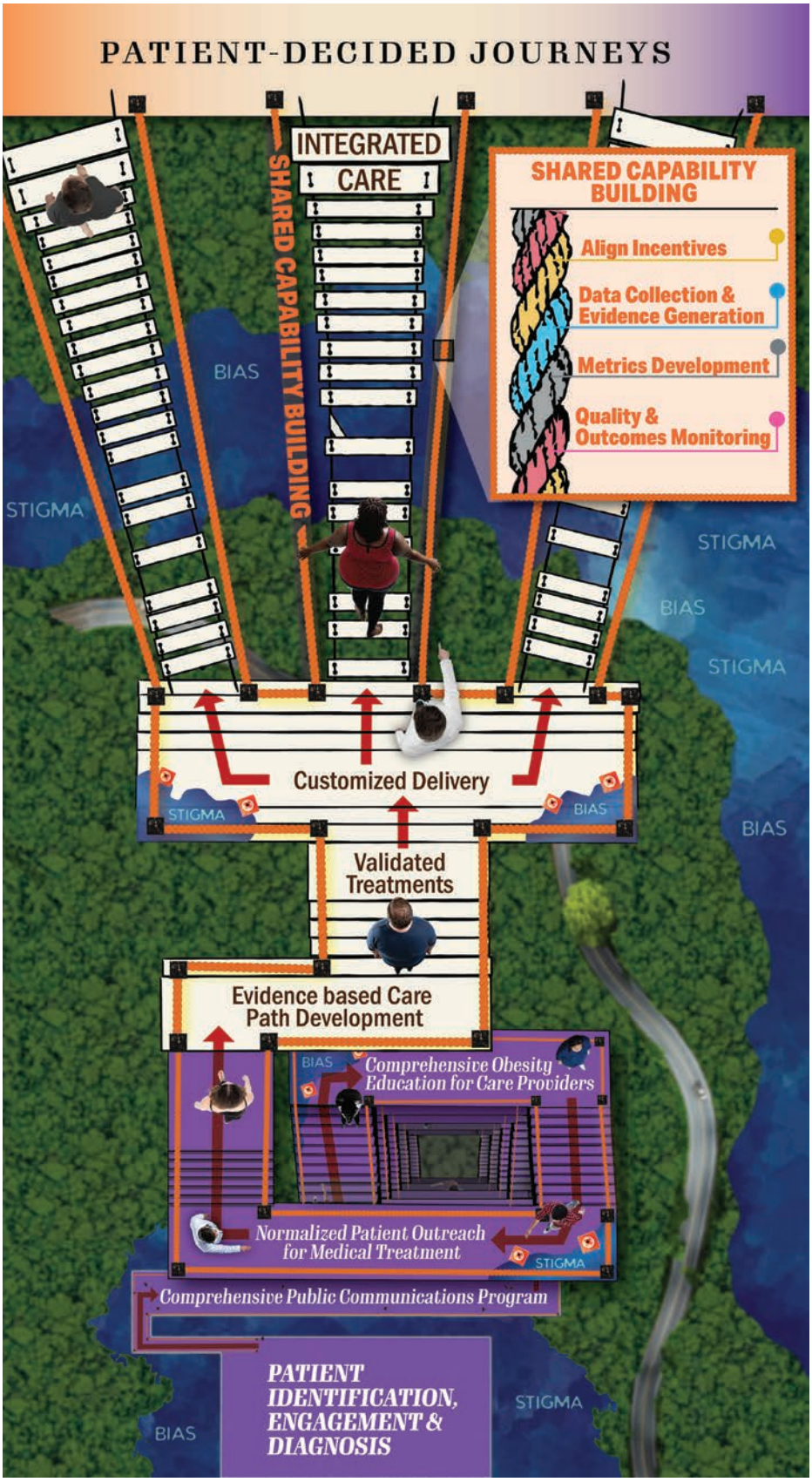


Figure 2: A Roadmap for transforming obesity disease management

Even before, and continuing throughout all aspects of healthcare for obesity, **bias & stigma (blue swamp)** will remain threaten patient access to obesity care. These treacherous waters must be waded through to start treatment, impede patient advancement and HCP engagement in the early stages of care, reduce treatment quality, and can easily swallow up patients who slip through the cracks of care capacity or weak healthcare infrastructure.

Solution Area I: Patient Engagement, Identification and Diagnosis (Purple staircase; contains 3 solution elements): Initiating interaction with the healthcare system is a challenging staircase for patients requiring effort to overcome bias and stigma and address this chronic disease with medical treatment. It is a joint effort, where HCPs must offer bias-free engagement and patients must be open to change. Both HCPs and patients are learning as they go about how to identify, diagnose and treat obesity. The staircase and then the progression to the bridges represent continuous, science-based improvement in an established **learning environment**.

Solution Area II: Shared Capability Building (orange rope; contains 4 solution elements): Depicted here as intertwined ropes and railings that support the other two solution areas. Where incentives are aligned so that metrics to set, assess and reward best practices are working well in tandem- a rope handrail for patients to grasp and trust. They also represents firmly established data collection and evidence generation structures that support monitoring practices for quality and outcomes that can be regularly updated.

Solution Area III: Integrated Care (Tan platform & bridges; contains 3 solution elements): Patients and their providers have multiple care pathways from which to choose that are based on evidence, and within which the specific treatments offered have also been validated. Patients also learn more deeply about what works for them and share decision-making to customize delivery of healthcare treatment and services. The very ground patients walk on, integrated care must navigate **capacity challenges** (represented by missing boards in the bridge, few HCPs along the paths) as well as important cross-institutional collaborations.

obesity care; regularly improving patient care in response to ongoing evidence development while managing current capacity constraints and equitable access to care.

The three systems-wide barriers, or health system readiness challenges weave through all aspects of our solution areas and have proven to be critical to the development of integrated, systemic change recommendations. Stigma and bias are primary: stigma against people with obesity is pervasive in our society, affecting patients' own identities as well as every person with whom they have contact. Bias starts when people don't understand obesity as a disease and thus people with obesity are treated with disrespect. Bias finishes with limited health care, and certainly healthcare that is not patient-centered. With such high numbers of people living with obesity, care capacity and disease state management capabilities will influence how, and who, receives care, both in terms of how care can be integrated and how the organizational structures are built out to accommodate our society's care needs. Traditional healthcare organizational structures are unprepared for the integrated (and varied) care pathways that comprehensive obesity care will require. All stakeholders require more information, including scientific evidence, patient experience and real-world data in order to build successful care pathways. As a whole, these systems-wide readiness barriers have been addressed as the team progressed from solution ideation to implementation recommendations.

1: Patient Identification, Engagement, and Diagnosis

Weight stigma and biases profoundly impact the initiation of medical treatment of obesity as a chronic disease. A study in 2018 found that a total of 96% of adults with obesity are not seeking any medical care.[6] Potential patients and their family members usually assume that high weight is a character flaw: care providers are often not trained to address obesity as a disease and thus do not understand how to identify and engage new patients in an informed and collaborative manner. When providers do engage patients appropriately, they are often not able to ensure that evidence-based care can be provided once a diagnosis has been confirmed, nor provide a patient with an integrated care plan.

Design Lab participants pressure tested a multi-component system solution for managing obesity as a disease. In the patient identification, engagement and diagnosis solution area, three important solution elements were offered as fundamental to initiate conceptual and attitudinal changes across multiple stakeholder groups (see Figure 3). The proposed solution elements include:

A. Create a comprehensive, public communications program
B. Establish pervasive obesity education for care providers across healthcare systems
C. Normalized patient outreach processes to initiate medical treatment for obesity care

As depicted in Figure 3 below, these three solution elements are fundamental aspects to establish if we are to create paths for patient engagement, identification and diagnosis. In the current environment, patients must overcome so much bias and stigma and may perhaps even follow paths that will lead them away from evidence-based healthcare for this disease. It is only by working

together to strengthen our health systems; by engaging and informing the public, by ensuring that care providers are up to date in their knowledge of this disease and ultimately, by normalizing patient outreach that we will be able to establish equitable access to the biomedical advancements available for obesity care.

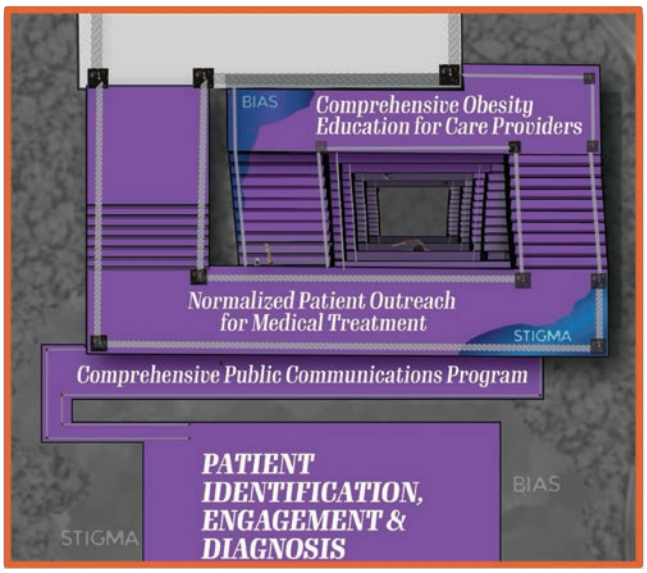


Figure 3: Solution elements of the first solution area, Patient Identification, Engagement, and Diagnosis. Initiating interaction with the healthcare system is a challenging staircase for patients requiring effort to overcome bias and stigma and address this chronic disease with medical treatment. It is a joint effort, where HCPs must offer bias-free engagement. Both HCPs and patients are learning as they go about how to identify, diagnose and treat obesity. The staircase and then the progression to the bridges represent continuous, science-based improvement in an established learning environment.

1A: Comprehensive Communication Plan: Obesity is a disease

People with obesity comprise over 40% of the adult population in the US, but far lower numbers are seeking medical care for this disease.[7] These low numbers have not dramatically increased despite medical research breakthroughs in obesity care. Fundamentally, our society has not shifted away from the public's understanding of obesity as a character flaw and toward acceptance of obesity as a disease.[8]

This attitudinal limitation does not just discourage potential patients; it also has slowed acceptance of healthcare providers, payers and policymakers that must learn to treat obesity as a chronic, heterogeneous disease.[9]

The public, patients and their families, providers, payers and policymakers all require evidence-based information that will shift our understanding of how and what people need to either prevent or treat this complex disease. The stakes are high: Obesity is a progenitor disease of many public health challenges that can be better managed if we improve our understanding and treatment of obesity.

A comprehensive, evidence-driven communication plan must reach multiple levels in society, depicted in Figure 4 below. The quality and trustworthiness of the messages (and the ability to "rise above the noise"), the breadth and depth of societal penetration, and the monitoring and measuring of success will support increased treatment and better outcomes for people with obesity.

Action Components of 1A) Comprehensive Communications Plan

Message Content: Tailored to specific audiences, evidence-based information about obesity must come from trusted sources that can convince people to reject a "calories in, calories out" approach to obesity management. No longer to assume it a character flaw, our general assumptions must look to medical science as the solution.

Breadth & Depth of Message Penetration: No one communication channel or message will suffice to create a paradigm shift to recognize obesity as a disease. Evidence-based information must be disseminated across multiple platforms simultaneously. For each audience, key institutions must engage to ensure that messaging is uniform, quality- assessed and appropriate for that audience. The messaging must address the realities of the current environment, where each audience has already been inundated with messaging about obesity and obesity treatments that are misleading or even scientifically incorrect. As depicted in Figure 4 below, public service announcements, print media, television and documentaries, medical societies' communications and conferences, social media platforms and school programs combined can penetrate society sufficiently to generate a paradigm shift in our assumptions about obesity and its care. Combined with an objective to debunk questionable (albeit widespread) information, a comprehensive messaging program will help shift the dialogue regarding obesity as a disease and obesity care standards of care.

Communications Metrics: Any communication plan will require metrics to judge what messages work and what level of message penetration in a community is necessary to effect change. While interim metrics will be required, ultimately, success can be measured if we can identify medical treatment increases in a geography after a communication plan is launched.

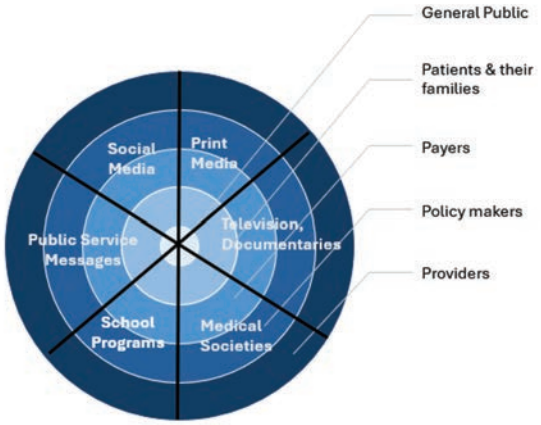


Figure 4: Comprehensive, evidence-driven communication plan: Obesity as a disease

1B: Obesity Education for care providers

In tandem with the broader communication recommendations outlined above, provider education (including pharmacists, GPs, nurse practitioners, specialists) must move forward uniformly

and expeditiously to ensure that people living with obesity can receive appropriate care to address this public health crisis. Providers must have medical science knowledge, patient journey information, coverage practices and a nuanced understanding of how, at this juncture in time, patients will require trauma-informed care to initiate medical care under their supervision.

This laundry list of knowledge content highlights the enormity of the task to educate healthcare providers (HCPs) about the chronic, heterogeneous disease of obesity and standards of care. The good news is that HCPs are in a medical science field for a reason; they are lifelong learners who have the skills and capabilities to adapt their behaviors as new evidence becomes available. In addition, the National Academy of Medicine supported a collaborative effort to define the core competencies for the prevention and management of obesity. This work can serve as a foundation to the comprehensive development of training for obesity care.[11] The challenges include how and where to reach HCPs, what scale and scope of training is needed, and what incentives can be introduced that will encourage a uniform shift in professional behaviors in the treatment of this disease.[11]

Action Components of 1B) Obesity Education

Build obesity identification and care into medical, nursing and pharmacy school curriculum:

The scale and scope of training requirements will remain an important factor in obesity care. Provider organizations, from the American Medical Association to the Obesity Action Coalition, to government bodies (e.g., the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)) are creating materials that support the kind of training currently required.[12] These organizations must team up with medical education programs (M.D., Nursing, and Pharmacy) to initiate early and widespread professional education efforts. Where appropriate, obesity education segments must also be integrated into other health education action components (e.g., in education about obesity-related diseases, obesity science must be included). A clear metric will be to increase these offerings, and track how many medical professionals take these training courses annually. For example, monitor the overall increase in obesity-trained medical doctors, nurse practitioners, pharmacy directors, registered nurses, and physician assistants.

- ❖ With new training action components in place, obesity training will also have to be included in licensure tests (e.g., the US Medical Licensing Exam (USMLE) for doctors and the National Council Licensure Examination (NCLEX) for nurses). Metrics for this education action component will be clear and easy to track in exam outcomes and will positively contribute to the existing HCP capacity challenges.

Implement obesity care coordination training programs at nursing schools:

Perhaps a subset of the educational objective above, training in care coordination for this chronic and complicated disease will be required. With so many obesity-related diseases and with such a high potential volume of patients, the coordination of medical interventions (e.g., surgery, medicines) and ancillary services (e.g., necessary behavioral health, dietician support, physical exercise and mental health programs) must be professionally addressed.

Create mandatory Continuous Medical Education (CME) training programs for the disease and care of obesity:

In this changing field, CME training will enable medical professionals to keep up with advancements in the field. Medical professionals will be best equipped to support the large population of people with obesity if this training is mandatory. Medical societies and care provider organizations must work together to develop and implement obesity as mandatory training. For example, there are new diagnostic codes and metrics for obesity that medical professionals should be trained to use. The diagnostic field is developing, soon to require more than BMI for diagnosis of the disease. Healthcare providers will have to a) be trained in the accurate implementation of additional measurements for diagnosis (e.g., waist circumference measurements), and; b) understand how these diagnostic tools are to be registered in electronic health records (EHR) and coded for reimbursement. The codes and metrics that define the disease are continuing to develop, and will in turn, influence access to different treatments. Patients will benefit as HCPs are able to understand how to use the diagnostic codes and metrics with their patients.

Educate health systems on federal accessibility and equipment requirements to provide care for people living with obesity (Rehabilitation Act, Section 504 final rule recognizes obesity as a disability).

1C: Normalize patient outreach to initiate medical treatment for obesity care

To normalize the initiation of medical treatment for obesity care, healthcare professionals and potential patients must share a similar understanding of obesity as a chronic, heterogeneous disease and maintain a basic level of mutual respect and trust. Because of the outsized role that biases, and stigma have held in our society, people with obesity have avoided engagement with medical professionals. However, the social, cultural, and scientific recognition of obesity as a chronic, progeniture disease can take hold. As a broad communication plan and comprehensive education for healthcare professionals outlined above progress, we expect that people with obesity will engage with medical professionals. In turn, medical professionals will have the appropriate language and approach to engaging people with obesity.[13] With a diagnostic entry point that respects the dignity of patients, these patients can begin a positive engagement with a healthcare system that recognizes obesity as a disease and understands the range of treatment options needed, from nutrition and physical activity to psychological support, to bariatric surgery and/or medications.

The medical science community and potential patients must be proactive to normalize medical care for the disease of obesity. Recognizing the size of the potential patient population, primary healthcare providers and their staff will likely be the entry point for new patients. As the primary care office transforms, they will benefit from organizing more efficient ways to update information on patients and normalize more systematic engagement tools. On the individual level, people with obesity must be prepared to engage and self-advocate to gain the most from medical care and ancillary services.

To have all treatment alternatives available to patients, downstream stakeholder challenges must be addressed, including the overall costs of care and the ability to adapt quickly to new information about successful care options for patient sub-populations. These challenges are investigated in subsequent sections of this document.

Action Components of 1C) Normalized patient outreach for medical treatment

Identify and engage new patients: Assuming deeper knowledge and understanding of obesity as a disease, HCPs must devise more welcoming engagement practices for new patients. In addition, payers, employers and other stakeholders can encourage people with obesity to seek medical treatment.

Consistent documentation of people with obesity by each HCP, where new patients will reliably know that screening and diagnosis of obesity will be documented over time, alerting the health system to the volume of medical needs and the risk levels for patients within each practice.

Create a pre-appointment checklist: To ensure efficient use of medical appointments, a pre-appointment checklist would allow patients to convey updates, goals and visit purpose prior to consultation. These forms could also confirm points of shared decision-making, such as what goals a patient is focused on and with what services they have already engaged.[14]

Develop patient information materials that outline obesity as a disease and obesity care options: To be disseminated by payers, employers and other community-wide health organizations (e.g., local policy makers, town/community traveling nurses, etc.), pamphlets that encourage people, in the comfort of their own homes, to reflect on advancements in obesity as a disease, how it can be managed and what personal goals they might seek to achieve.

2: Shared Capability Building

Logistical changes will be required in the early stages if obesity care is to be transformed. Currently, health systems face infrastructure challenges that act as gatekeepers to the smooth transition for patients from identification and diagnosis through to full engagement with the appropriate healthcare support. Shared capability building requires that the following solution elements are addressed (see Figure 5):

A. Metrics development
B. Quality and outcomes monitoring
C. Data collection and evidence generation
D. Align incentives across stakeholders

As depicted in Figure 5 below, Shared capability building covers the deep infrastructure that steadies the patient, and the healthcare system itself that provides support. Metrics must be up to date, with quality measures and coding that allows providers and payers to understand how patients are treated, and what treatments work best. Healthcare stakeholders must have a system to monitor the quality of care and the outcomes for patients. The collection of data must be robust so that the evidence generated will continue to build knowledge of this disease. Incentives for stakeholders must be structured to align around common objectives and contracts established that build data and embrace the evidence developed.

Figure 5: Solution elements of the second solution area, Shared Capability Building. Represented here as an intertwined infrastructure that supports the other two solution areas., where incentives are aligned so that metrics to set, assess and reward best practices are working well in tandem- a rope handrail for patients to grasp. This rope represents firmly established data collection and evidence generation structures that support monitoring practices for quality and outcomes that can be regularly updated

2A: Metrics development

Critical to systems change is the infrastructure that allows providers to communicate medical needs to payer organizations. Coding and quality measures that support a bias- and stigma-free patient induction process are developed in alignment with clinical guidelines and standards of care (see Box 1 below). As obesity treatment continues to develop, these evidence-based coding systems will support patient journeys—from screening and diagnosis, through various stages of treatment across the whole patient journey. To ensure this future state, coordinated action across many expert groups is necessary and the coding systems must shift over time from tracking identification to tracking and rewarding health outcomes. Through each stage, patients must be part of the expert groups influencing coding updates.

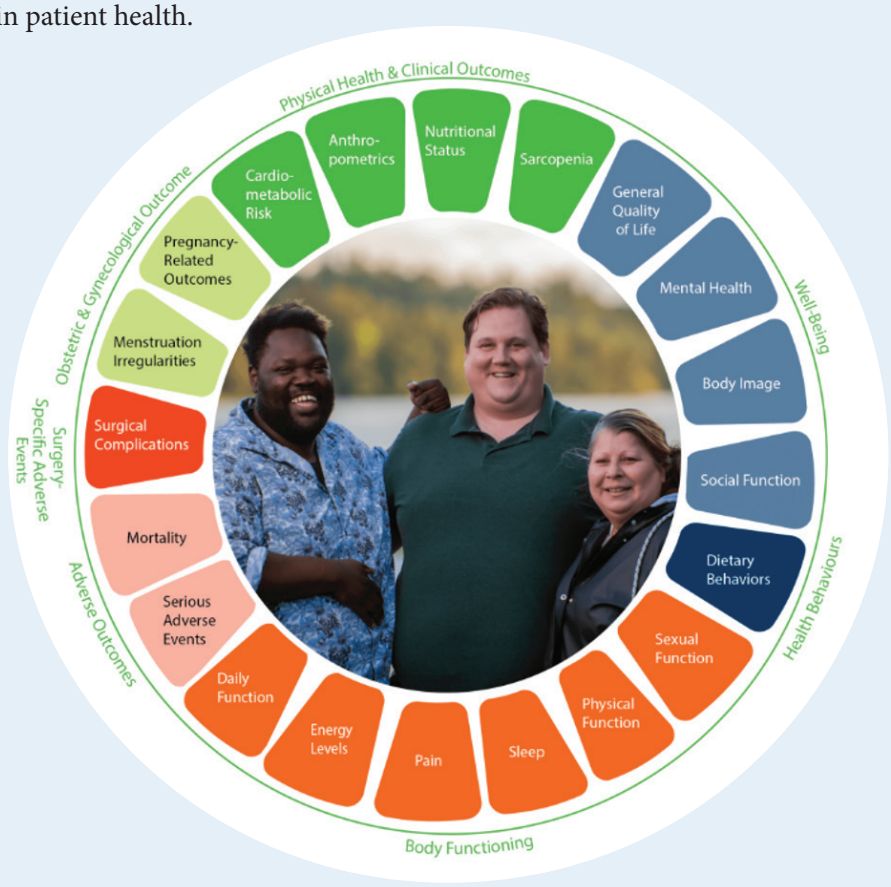
There are many important institutions working to establish evidence-based procedures for obesity care, but there remain gaps in how medical science advancements are integrated into care practices. For example, while the medical science evidence confirms obesity as a chronic, heterogeneous, progenitor disease, providers are not systematically documenting a patient's primary diagnosis as obesity.[15] There are likely several reasons that documentation is haphazard, including HCPs who assume that using codes for obesity will not trigger reimbursement for care.[16] HCPs and patients may also continue to hold biased attitudes, assuming that patients are not suffering from a disease state but rather a lifestyle choice, rendering treatment a nonissue. Across all considerations, the patient with obesity, when not diagnosed for obesity as the primary disease, is unlikely to gain access to the full range of ancillary services (in addition to medical treatment) that are proving necessary to full obesity care. We are at the beginning of a process to bring people with obesity into medical care. As more people with obesity engage healthcare systems, we can move beyond

a basic recognition of obesity as a disease. Moreover, once medical records document obesity screening and diagnosis consistently, we will be better able to track the disease at the population level, building our knowledge of this chronic disease and how to treat it.

Of course, to systematically document obesity in medical records, the codes to do so must be aligned with current medical knowledge and standards of care. In October 2024, new ICD-10-CM codes for adult and pediatric obesity were released (see Table 1) by the Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS). These annual updates are meant to reflect up-to-date healthcare practices, but at this time, codes for obesity remain tied solely to BMI calculations.[17,18] Because these codes remain tied to BMI, they are insufficient to support the patient and providers, who need more specifics to organize appropriate clinical treatment. Limited as such, existing codes do not signal to the system to initiate all the actions required to fully diagnose, track and treat patients.

Box 1. The International Consortium for Health Outcomes Measurement (ICHOM): Where value-based health care is based on patient health outcomes.

ICHOM measures patient health outcomes to drive value improvements across health systems. ICHOM establishes patient-centered outcome measures in specific disease areas, including Obesity. As quality measures for obesity continue to develop, ICHOM obesity outcomes measures can support a system that rewards providers for documented improvements in patient health.



In the absence of clear, differentiating codes, stakeholders across healthcare systems are innovating; they are finding ways to identify stages of the disease of obesity to provide more nuanced diagnosis, care and access. For example, beyond a straight clinical assessment, the Social Determinants of Health (SDOH) can impact a current health condition as well as the available opportunities to engage a full panoply of care services. A SDOH risk score could be a welcome addition for providers to understand their patients' needs and care options. Other codes or scoring practices can also be helpful, from assessments of disease severity to measurement of adherence to treatments; these collections of codes are important to maintain in a transparent and developing context, so that experts are able to collaborate around what codes or metrics work well for what purpose. As the wealth of patient assessment tools increase, the evidence-based taxonomy of tools must remain transparent for all stakeholders.[19]

New E-Codes	Obesity Severity	BMI Range (kg/m2)
E66.811	Class 1 Obesity	30 to less than 35
E66.812	Class 2 Obesity	35 to less than 40
E66.813	Class 3 Obesity	40 or greater

+

Adult BMI Z Codes	Adult BMI
Z68.25-Z68.29	25-29.9
Z68.30-Z68.39	30.0-39.9
Z68.41	40.0-44.9
Z68.42	45.0-49.9
Z68.43	50.0-59.9
Z68.44	60.0-69.9
Z68.45	70 or greater

Table 1: from the New Adult Obesity ICD-10-CM Codes Partner Promotion Materials, Version 2 Updated 11/1/2024 (See New Adult Obesity ICD-10-CM Codes Partner Promotion Materials)

Action Components of 2A) Metrics Development

Integrate training around obesity-related coding and billing procedures in medical education programs.

Build improved and non-biased obesity coding system (ICD-10-CM codes and others), that go beyond BMI, encouraging their use to establish appropriate monitoring of obesity as a disease and links to payers (i.e. reimbursement).

Engage all Coding and Coding assessment agencies to coordinate their updates to codes for obesity. As obesity metrics evolve beyond BMI alone, the next annual update to the ICD-10 codes should be revised to reflect the changes.

- ❖ New codes for obesity will necessitate Electronic Medical Records (EMR/EHR) to accommodate these new measurements, such as waist circumference, weight-to-height ratios, etc.

Identify and coordinate the diversity of coding and metric innovations that are under development: work to navigate the pool of information available beyond BMI assessments and pool the information to prompt the best use of evidence for patients, providers and payers.

2B: Quality and Outcomes Monitoring

Quality measures are an important next step in the documentation of obesity as a disease and its treatment. STAR ratings and HEDIS measures for obesity are currently set to document and assess how health plans and providers manage obesity. HEDIS measures and STAR ratings are used to track the appropriate screening, diagnosis and treatment of patients with obesity and these measures incentivize payers and providers to apply standards of care in patient care.

Quality measures for obesity in use today remain limited, but several organizations are testing quality measures to document obesity process measures (e.g., registering a diagnosis, documenting weight gain over time).[20] Ideally, quality measures that are used by payers and providers will continue to shift along a continuum. First, quality measures can encourage patient identification, rewarding care providers who are best able to engage patients (i.e., process measures). Once patients are well documented and patient induction is normalized, additional quality measures can incentivize providers who are able to bring high numbers of patients through to treatment options. Finally, quality measures will be able to reward providers that can measure rates of positive health outcomes for patients (including both patient outcomes and patient satisfaction scores) after treatment interventions.[21]

Action Components of 2B) Quality and Outcomes Monitoring

Develop a strategic set of peer-reviewed articles that bring attention to the current state of coding and quality measures; how/ how frequently they are used to establish a baseline, primary diagnosis for people with obesity; how/ how frequently diagnostic codes trigger reimbursements.

Build partnerships across scientific agencies and institutions focused on obesity care improvements: share data, coordinate evidence development and build processes to speed updates to guidelines, standards of care, coding and quality measures for obesity.

Create NCQA behavioral health awards that recognize quality obesity care programs.

Partner to develop an NCQA-sponsored Innovation Summit focus on Obesity.

2C: Data collection & evidence generation

As more people with obesity seek medical care, and more manufacturers develop obesity management medications to address this disease, data will continue to expand, supporting stronger evidence-based treatment pathways. Clinical trial data, electronic health records, medical claims data, and patient reported outcomes will all improve our knowledge regarding obesity care. Yet, there remain gaps in our knowledge that must be proactively addressed. Some of our current data gaps will be resolved over time, as more long-term outcomes from RCT and real-world data become available. Other knowledge gaps are reinforced by institutional constraints, be it ownership of data, or patient privacy challenges that limit our ability to analyze across electronic health records (EHR) and medical claims data. While data limitations are not unique to obesity management, these gaps can be particularly challenging as this field continues to grow. Data sharing will remain central to improving healthcare across the full patient journey.

Given the urgency of the need for data to inform and improve evidence-based patient journeys and health outcomes, it may be expedient to first articulate the most urgent questions we need answered and then work to resolve or align data sources that can help with the specific investigation. The next step would be to identify public and private data sources that might be well situated to engage.

There is general agreement that sharing evidence systematically over extended time periods would be a great asset for obesity-related research and for continued quality improvements in obesity care. Yet no best practice exists that models a public-private data partnership that has led to a unified effort to generate data and share outcomes broadly. The National Institutes of Health (NIH) provide some infrastructure, but the research they support is spread across various NIH centers. A regular effort is made to engage across these groups, but that does little to foster creative solutions nor to share results of their work more broadly. The Nutrition Obesity Research Centers (NORC) were established to foster interdisciplinary research in obesity as a population health crisis, funded by the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK). These eleven centers provide pilot funding, expertise and resources to build these institutions, a promising foundation for data creation and publications.[22] Another effort advanced with government funding sits under the umbrella of the Patient-centered Outcomes Research Institute (PCORI). PCORI's Clinical Data Research Network (CDRN) brings public and private research institutes together, funding three priority conditions, including obesity research. These collaborations have led to more publications on obesity.[23]

These efforts are important, but more investment is needed to build an integrated community of research. In addition, the research must take many forms,[24] from randomized clinical trials, real world data and clinical decision support, to improving guidelines and standards of care; practical uses of evidence that will have immediate impact on our knowledge of obesity care while lessening the impact of bias and stigma. In this less siloed environment, we must expect that more evidence will elevate decision-making and improve patient-centered care.

Action Components of 2C) Data collection & evidence generation

Embrace the current chaos: With evidence-based dialogues, clarify specific data and analysis that is needed to a) move to clarity about the differentiating factors that characterize disease severity; b) convey to patients what illnesses threaten their health, based on their specific disease profile.

Encourage development of an aggregator marketplace: a burgeoning business model, companies are emerging that take on the task of mining various data sources to produce outcomes-based evidence that will support standards of care in obesity.

Establish bridges across public-private partnerships to collect and share data across institutional boundaries. There exist several broad efforts to increase obesity research. Creating opportunities for leaders in these institutions to share and potentially coordinate research objectives could build the evidence generated more strategically.

Create evidence generation and evidence-sharing channels that allow health systems infrastructure to be updated more quickly (e.g., clinical guidelines, coding systems beyond BMI and clinician education programs).

Data collected meets requirements at different levels of sophistication. For example, certain aspects of the validated treatments might need only a meta-analysis, while genetic analysis might require more substantial data, e.g., AI data analytics.

Include patient-reported outcomes in data collection processes. For example, patients may report different outcomes across different geographies. Such outcomes data can then inform care for patient sub-populations.

2D: Align incentives across stakeholders

Healthcare stakeholders, including patients, providers, payers and manufacturers, all share one key goal: to improve patient health. The challenges are at the systems level: when we look at populations of patients and multiple diseases, the alignment of incentives becomes complicated, especially to align across all healthcare stakeholders. In this case, the chronic, progenitor disease adds additional complications, whereby people with obesity present with varying combinations of obesity-related conditions and/or care needs that introduce a high level of heterogeneity in treatment options and outcomes. In addition, treatment guidelines take time to build, and until a new consensus is reached, coding and quality measures will not advance substantially. As a result, obesity care will not be transformed, and patients will not gain the benefits of these medical science advances. If we continue with incentives that are not aligned across these stakeholder groups, it will be difficult to assess what is working for patients: what treatments, including medical, surgical and ancillary services, will help reach that shared goal, to improve patient health?

When incentives are aligned, then healthcare stakeholders (patients, providers, payers and manufacturers) can balance their shared incentive with other responsibilities. In other words, aligned incentives allow for shared capability-building and the sustainable transformation of obesity care. People with obesity want the best care but balanced with other personalized health objectives and life goals. Providers want to facilitate health and healthy decision-making while recognizing the full patient context. Payers are in business to improve patient health but balanced across all disease areas without increasing costs. Manufacturers want to improve patient health, but not just for one disease so that they can invest in R&D for the next medical science breakthrough.

Obesity was designated a disease by the FDA in 2013 and medical science breakthroughs since then continue to stabilize this definition.[25] Yet rather than building toward clear standards of care, or the ideal patient journey, we are still expanding our understanding of treatment success and still wrestling with obesity as a disease, and weight as one symptom of that disease. As a result, stakeholders cannot dictate a narrow set of actions that will bring results. In fact, even the results sought remain varied: should payers be measuring reduction in progression to diabetes, NASH or CV events? At what time intervals? Would it be better to measure % reduction in body mass? To do so, would it be necessary to push for a doctor's visit to assess, or would self-reporting be acceptable? These are only some of the many questions that remain, which, when answered, can improve patient care

To truly align incentives so that the shared goal—improved patient health—can be measured and met, all stakeholders need to have a "common language" that will allow them to agree on health outcomes that are understood, simple enough to measure, and can be tracked with the data at hand. In self-contained healthcare systems, medical claims might provide sufficient information

(e.g., BMI) on a monthly basis so that weight loss can be tracked. Comparing that data to the services provided can show what treatment regimens produce overall results (e.g., beyond BMI/weight as a proxy for obesity, and including improved mobility, decrease in sleep disorders, etc.). Over time, subscription models can be offered which steer patients to care pathways that have had success.

Once treatment regimens that produce results are known, larger payers will want to incentivize patients to participate in treatments that will bring that patient their best results. However, incentives would also require that patients who do not comply with the care pathways lose access to an aspect of care. For example, if patients are encouraged to engage in ancillary services, but they do not, they may lose access to obesity management medications. The problem is that payers negotiate discounts based on volume of sales. These discounts are an important tool to maintain reasonable insurance coverage rates across the system. If payer subscription models limit the use of one specific obesity management medication, they could risk these mechanisms that keep insurance costs low. Payers also encourage patients to utilize the best care available, as they balance their patient populations' overall healthcare needs.

Under the objective of aligning incentives that impact obesity care, we must also recognize the current direct and indirect costs incurred when people with obesity are left untreated for the disease. In 2020, the Milken Institute estimated that the economic and social costs of obesity as a disease to our healthcare system at just under $1.4 trillion per year.[26] With the rates of obesity increasing annually, these costs have only increased over the past five years. We can certainly recognize that incentives must align to reduce the cost burden to our healthcare systems by improving overall patient health.

At the same time, treating obesity also incurs costs to healthcare systems. These costs are partially offset by savings from improved population health and by changes in the marketplace itself. Research shows that cost offsets in Medicare alone would save "as much as $245 billion in the first 10 years of coverage alone, if private insurers were to follow Medicare's lead."[27] In addition, public data suggests that manufacturers are effectively engaged with payers on pricing negotiations[28] and federal government forecasts this dynamic will continue based on general market forces and, specifically, from increasing competition. As more medicines enter the market and as patent expiries begin, market competition will bring US prices down. In addition, those manufacturers that already have an obesity medication in the market have taken actions to provide flexibility to patients, including building contracts where aligned incentives support increasing and durable access of patients to these new treatment regimens.[29]

So how can we facilitate further and broader incentive alignment to build good patient care? Recognizing current limitations, what small steps forward might come first? Manufacturers, payers and large employer healthcare systems have already started by creating pilot programs where the scope of medical treatments and ancillary services are offered across a set patient population (Figure 6). They are learning more about patient behaviors and data requirements to support a robust analysis of the pilot programs. Leaning into patient care, these organizations are supporting real world data generation that will further our understanding of excellence in obesity care.

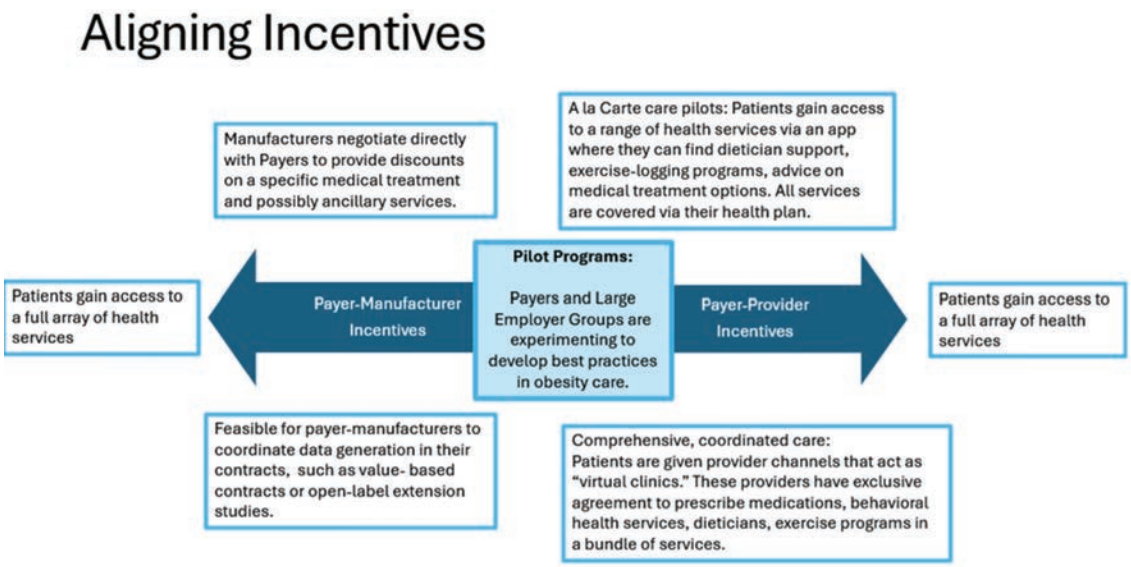


Figure 6: Experimentation by payers and employers to develop best practices in obesity care

Aligning incentives in practice

As this new era takes hold, payers and providers can expand contracts which incentivize appropriate treatment and a willingness to treat obesity as a disease. These contracts may take different forms but would be grounded in clinical standards of care and set up to collect data to further our understanding of the combinations of treatments that are most successful for patients. Moreover, these contracts would serve to link payments to disease management practices, incentivizing continuous learning and improvement in patient care over the long-term. Some viable contract options include:

A. **Tiered care volume contracts:** Until social norms recognize obesity as a disease without bias or stigma, providers and payers could negotiate based on "willingness to treat" whereby care providers would receive incentive payments based on the % of their total obesity population that they are actively treating. As providers reach higher percentages of patients with obesity in treatment, they would receive a higher reimbursement per patient. Other triggers for larger payments might include outcome measures, where patients achieve cholesterol or glucose level changes, improvements in mental health and/or agility function improvements, or patient-reported quality of life improvements. Tiered contracts would encourage treatment to standards of care, while reducing the stigma and bias now associated with this chronic disease. Such contracts would also require clear identification of the patient population to be treated, supporting a more systematic approach to identifying and retaining patients, as well as developing systems to monitor disease management.

B. **Subscription models:** Payers and providers have begun to pilot a proscribed patient journey, with a limited range of older medications and **new obesity management medications** provided for a defined population and with the requisite ancillary treatments included. In this case, the stakeholders would contract based on expected population size and target health outcomes. Subscription models can support evidence generation to understand how an **obesity management** medication works with what combination of ancillary treatments for specific subpopulations. With the patient population identified in advance, this model supports a

more systematic approach to identifying and retaining patients, as well as developing systems to monitor patient outcomes. Yet at this time, the population of people with obesity who will seek care is still unclear. Without a clear understanding of patient volume, it will be difficult to agree upon a price per subscription. Until the patient population seeking care stabilizes,[30] subscription models remain challenging to nail down. One recommendation would be to tier the subscription contracts based on population size, where the price per patient would differ by volume tiers.

C. **Bundled Programs:** Payers and providers would contract with a third party to provide access to the range of targeted interventions, with patients paying a fee-for-services utilized across the range of intervention elements. Such programs would increase the opportunities for obesity care and support to develop, especially now as patient surges are expected. Third parties could also contribute to the knowledge of what combination of services are most requested and how they are utilized by patients to the best effect. Bundled programs would have to remain tied to healthcare providers to oversee progress toward their goals (e.g., weight loss, reduction in obesity related diseases, improvements in sleep, or improved mental health). Such programs might also then enable providers to go at risk for their patient population outcomes.

    1. A subset of bundled programs, "manufacturer direct" contracts are initiated by manufacturers seeking to work directly with provider organizations. Already in pilots, manufacturers endeavor to provide incentives (i.e., discounts) directly to the provider and/or patient, while also building a range of ancillary services into the contracts. Manufacturers are motivated to design programs where their medications are made available following treatment guidelines and where rebates can be provided more closely to the patient. Providers will seek longer contract terms (e.g., 3-year contracts), as they would not include these medical treatments in their PBM negotiations, losing any possible rebates in this disease area for the normal PBM contract period.

    2. Another subset of bundled programs might include an "a la carte" option, where providers make available a range of medical and ancillary services for a set patient population. While the services are covered, it is up to the patient to identify the appropriate range of medical and ancillary programs in which they will engage. Payers in this case would delegate the menu of services to provider groups. Providers might then engage patients to identify a specific range of services. In these cases, payers would require less direct oversight, but patients and providers would likely share decision-making over treatments and services.

D. **Outcome-based contracts:** Traditional outcome-based contracts are challenging in the context of uncertain care pathways and heterogeneity of patient needs. Obesity care is still in transition, where what to track remains in flux. As broader access and patient population size stabilize, payers, providers, PBMs and manufacturers will be able to agree upon what outcomes to track. Finally, outcome-based contracts will require the coding infrastructure and the claims data to be well established and accessible before stakeholders would agree to these arrangements.

In terms of data generation, all stakeholders, (especially patients, providers, payers and manufacturers) must contribute to generate data to advance obesity care. The data generated initially will be heterogeneous due to experimentation, evolving approaches, and local capabilities. In addition, we expect that the roles for healthcare providers and other stakeholders will shift. For example

coordinating the broad range of ancillary obesity care services, will require increased healthcare provider engagement. Aligning incentives, analyzing best practices and encouraging all stakeholders to coalesce around improving patient care will move obesity disease management towards a learning healthcare system.

Action Components of 2D) Aligning incentives

Continued experimentation: Stakeholders, from patients to providers, payers and manufacturers, share an interest in improving patient health. Stakeholders must continue to experiment, designing programs that improve health outcomes in well-defined, data-rich environments that contribute to our knowledge of obesity care and the necessarily varied patient journeys.

Share research/outcomes from private contracts: All stakeholders can benefit from other's experiences. Sharing outcomes from various contract models; what encourages best adherence? Best outcomes? How will maintenance periods be best structured in the patient's journey? What results to measure before deciding to shift to maintenance therapy?

Build a resource navigation tool to share information and decision tools: Currently, bespoke programs are developing but they are siloed. A means for sharing key information is needed, including outcomes data, patient journeys, sub-population identification tools and effective patient engagement practices.

3: Integrated Care

In this third solution area, we build on the systems-wide solutions outlined for patient identification, diagnosis and care, and the shared capabilities required to move the systems forward. Integrated care options make concrete how obesity care can be organized and delivered, as an outgrowth of the infrastructure changes outlined above. To provide people with obesity the comprehensive, integrated care options necessary to produce long-term results, we propose enhancing health systems in three ways (Figure 7):

- Offering **a validated set of treatments and services** that support the best health outcomes for each sub-population and that recognize patient preferences in socio-economic context. These treatments and services must be assessed with data and evidence that (progressively, over time) is analyzed and critiqued by experts who share and discuss results in order to validate the treatment and services to be offered. These validated treatments that are offered would cover the full set of services for obesity management, recognizing and shaping how care is provided. Elements to be actively engaged will include nutrition services, physical activity programs, food provision, comorbidity management, psychological support services, and medical treatment.[31]
- **Evidence-based care path development** that nuances sub-population standards of care based on disease severity. In this heterogeneous disease, evidence-based care path development will be designed to support patients at different stages of their disease and recovery, recognizing that this chronic condition will not follow one, set path over time. Moreover, these care pathways must recognize access challenges that differ across patient sub-populations.

- **Customized delivery** in a shared decision-making process, where patients' environment, culture and socio-economic conditions are considered when customizing their care pathway. In customizing delivery of care, providers must accommodate access and capacity challenges.

In Figure 7 below, the first two enhancements (validated treatments and evidence-based care path development) would likely be encapsulated and disseminated in treatment guidelines, standards of care and (eventually) codes and quality measures. The customized delivery enhancements would be decided in a local, shared decision-making context among payers, providers, and patients. As telehealth and digital applications that create touchpoints with patients are embraced, tailored delivery enhancements that save time and travel will support more equitable access to obesity care. Ideally, data from the local level would be developed and used to inform clinical standards of care, establishing an ongoing learning process that will advance care over time. Together, these three health system enhancements will establish an appropriate approach to comprehensive obesity care management systems.

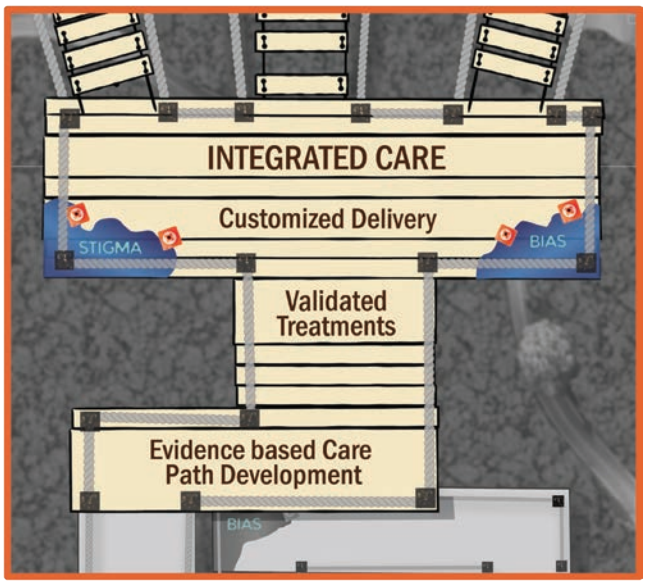


Figure 7: Solution elements of the third solution area, Integrated Care. Where patients are assured that care pathways in place are based on evidence, and the specific treatments offered have also been validated. Patients also learn more deeply about what works for them and share decision-making to customize delivery of healthcare treatment and services. The very ground patients walk on, integrated care must navigate capacity challenges (represented by missing boards in the bridge, few HCPs along the paths) as well as important cross-institutional collaborations.

3A: Validated treatments

With obesity firmly understood as "a serious, chronic, relapsing and treatable disease"[32] with a complicated range of obesity related diseases, treatment is not complete with medicine or surgery alone. Currently, obesity medication labels awarded by the FDA identify medicines as "adjunct" to diet and exercise regimens.[33] These treatment recommendations should based upon sufficient evidence to be considered validated. Complications of obesity, including obesity related diseases, are wide-ranging, and patients often have more than one additional condition (see Figure 8 below).

With such a heterogeneous disease, weight loss is one important aspect of the patient journey but does not address the disease comprehensively.

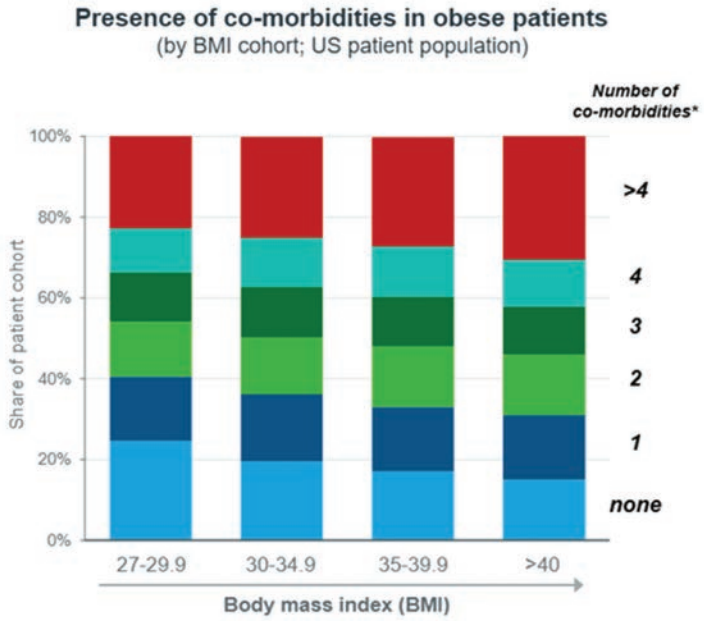


Figure 8: Obesity-related disease rate suffered by patients with obesity (taken from Gores, M., "When the dust settles: The future shape of the obesity market," IQVIA Blog, May 13, 2024)

To achieve comprehensive obesity care, the validated treatments will be based on a patient's needs holistically, including required treatment intensity and patient engagement. In addition, patient needs will shift over the course of treatment, with more intense use of certain services early (or later) along the patient pathway. Elements of these validated treatments are included in Table 2 below:

Culture of care	Active engagement programs	Psychological support services	Medical treatment elements
• Patient encouragement (motivation & care planning) • Patient navigation (access)	• Medical nutrition therapy • Dietary plans, consults • Food provision, food access • Physical activity / fitness monitoring • Obesity-related diseases management	• Behavioral health access • Mental health programs • Peer mentoring	• Intensive Behavioral Therapy (IBT) • Obesity medications • Metabolic surgery and devices

Table 2: Elements of validated treatments

In addition to these validated treatments, the overall integrated care must conform to standards of care that combines clinical guidelines with integrated care elements and systematic tracking of outcomes measures. Over time, integrated care design will improve as clinicians and other obesity care specialists continue to assess evidence and update the most effective patient care pathways. Coordinating these integrated care elements is a key design element for care delivery structures that we expect will require significant development. Some level of clinician authority will be necessary to oversee the integrated use of the validated treatments and to encourage appropriate transitions in care over time as more evidence develops.

Action Components of 3A) Validated treatments

Share research results that assess ancillary services' use and effectiveness. These results can be used to further standards of care and patient/provider incentive programs. The evidence generated can bind best practices to healthcare service delivery, speeding the process of care improvements.

Publish a quality review of telehealth and digital technology (e.g., apps) that support customized delivery of obesity care while maintaining care quality. Identify and establish institutional networks between app developers and patient/ provider organizations.

3B: Evidence-based care path development

The validated treatments will provide the foundation for positive health outcomes for patients with obesity. At the same time, evidence-based care path development — the sequenced use of the validated treatments based on disease severity – will best serve patient health equitably when the systems of care are organized to measure what works and use that knowledge to improve patient care interventions over time. Payers and providers may best support patients by:

1. Basing programs on expert-designed standards of care in obesity care; and
2. Segmenting patient populations by disease severity, number of obesity related diseases, and the patient's level of engagement or other characteristics that may refine the treatment regimen.

To ensure that care pathways are evidence-based, standards of care must be shared broadly and integrate HCPs approach to obesity care (see Box 2, below). With clinical standards of care clear and up-to-date, patients can be supported in their health journey by providers who have overcome biased and stigmatized approaches to patients, and adhere to known treatments to address the complexity of this disease: the elements of validated treatments outlined above will be combined differently in patient journeys, but always along expert-developed standards of care. Evidence-based care pathways will advance over time, recognizing changing patient conditions and as clinical evidence continues to mount.

- Evidence-based care path development might assess patient needs based on the severity of obesity or coding that goes beyond BMI, combined with risk scores that identify challenges beyond the clinical, e.g., social determinants of health, adherence to treatment, or the number of obesity-related diseases, and the patient's level of engagement. At the diagnostic phase, care systems require clear strategies for identifying and supporting patients to seek care, with transparent methods for differentiating access to care once the patient's needs have been diagnosed. As discussed above, ICD-10 codes have recently been updated for obesity. However, the

Box 2: Clinical guidelines, recommendations

With such a complicated chronic disease as obesity, many medical associations have weighed in with guidelines and recommendations for treatment since the American Medical Association designated obesity as a disease on 2013 (see below for a current list of organizations). Earlier guidelines established consistent steps for clinicians, and recent updates have included the new medical treatments available, the FDA labels granted, and weight-related complications to be considered in establishing comprehensive patient care.

Each guideline or recommendation considers diet, exercise and behavioral modifications as a mainstay of all obesity management approaches. There remains agreement that BMI measurement is recommended to initiate evaluation and determine disease classification, but for a full diagnosis, a clinical assessment of weight-related complications and waist circumference measures are recommended.[i] Obesity medications and bariatric surgery can also be considered in combination with behavioral changes and increased physical activity. Evidence shows that when medicines (specifically GLP-1s) are used in tandem with behavioral modifications, greater and more sustained weight loss is achieved.[ii]

Preventive care is also addressed in the guidelines. It is recommended that patients who are overweight stop gaining weight or lose weight to avoid progression to obesity and additional comorbid conditions. As identification of patients at risk for, or experiencing obesity, is very often first identified via a PCP office, the American Academy of Family Practitioners has also developed a comprehensive overview of clinical guidance and practical resources about obesity for PCPs.[iii]

List of organizations providing guidelines and/or recommendations since 2013:

- 2008: The Obesity Society published their first statement designating obesity as a disease.
- 2014: The American College of Cardiology (ACC), the American Heart Association (AHA) and The Obesity Society (TOS) joint clinical practice guidelines.
- 2016: The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE), jointly published evidence-based clinical practice guidelines.
- 2021: The American Heart Association.
- 2022: The American Gastroenterological Association (AGA) issues new clinical practice guideline on pharmacological interventions for adults with obesity, they identified the specific OM in their report.
- 2022: American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) updated clinical guidelines to expand patient eligibility for weight-loss surgery, now to include surgery for individuals with BMI >35 and for a BMI of 30-34.9 with metabolic disease.[iv]
- 2023: The American Academy of Pediatrics.
- 2023: Guidelines from the American Diabetes Association were updated.[v]
- 2024: The Obesity Medicine Association updated a tool for clinical practitioners, "the 2024 Obesity Algorithm®" that includes advice on starting an obesity medicine practice and how to use telehealth options.[vi]

References

i. Cornier, M., "A Review of Current Guidelines for the Treatment of Obesity," 12/14/2022. Am J Manag Care. 2022;28(suppl 15):S288-S296. doi:10.37765/ajmc.2022.89292
ii. Ibid. See also Cornier's references 1,2.
iii. Obesity Clinical Guidance | AAFP
iv. Kissin, R. "After 30 Years- New Guidelines for Weight Loss Surgery," news release from the American Society for Metabolic and Bariatric Surgery (ASMBS), 10/21/2022. After 30 Years — New Guidelines For Weight-Loss Surgery - American Society for Metabolic and Bariatric Surgery (asmbs.org). Accessed online 8/21/2024.
v. American Diabetes Association regularly updates recommendations on standards of care. See the 2023 Obesity Treatment and Weight Management Standards of Care for the Prevention and Treatment of Type 2 Diabetes—https://pubmed.ncbi.nlm.nih.gov/36507637/
vi. Obesity Algorithm | Obesity Medicine Association

debates continue: with continued evidence generation and improved medical education, HCPs might use BMI in tandem with a waist-height circumference measurement that will be coded and authorized.[34]

As more evidence accumulates, integrated care for each subpopulation of patients can be improved, with health outcomes data that will be reflected in changes to the care recommended as the disease reaches lower levels of severity (or with chronic resurgence of disease). The process of regular integration of new evidence and standards of care into care pathways will remain a complicated project, but the benefits will be significant. Patients and providers will be engaged in obesity management practices that will have incorporated more comprehensive diagnostics earlier, and more nuanced care pathways that were developed with evidence and provided without bias in partnership with patients. The validated treatments, evidence-based care path development, and patient journey phases (diagnosis, induction treatment, maintenance treatment) should interact to create differentiated 'ideal' care paths for each sub-population over time that vary in the number and intensity of interventions.

Action Components of 3B) Evidence based care path development

Build patient journeys for obesity sub-populations that are based on analysis of successful utilization of the full, validated treatments and are structured to respond flexibly to new evidence.

Work with relevant medical societies and patient associations to establish regular and timely updates to standards of care, in consideration of new evidence.

3C: Customized delivery

In the short-term, effective medicines and care pathways for this complicated disease will become more robust, and patients will also be more knowledgeable, as stakeholders (patients, providers and payers) accept obesity as a disease that requires medical attention and support. With more confidence and increased collaboration, people with obesity will share in the decision-making process that structures the care they will receive. Appropriate elements of the validated treatments will be offered, but it is the patient with their provider team who can best understand what additional flexibility will be needed in service delivery. The customization of how services are delivered will be influenced by practical considerations of daily life and socio-economic circumstances (see Table 3).

Patient's level of knowledge, readiness for treatment, personal preferences	Patient's access constraints
• Stigma & bias history • Cultural differences, racial / ethnic preferences • Readiness to change • Peer and family support level • Learning style • Time of life (work/ family responsibilities, availability for travel) • Self-care advocacy capabilities / trauma-informed care needs	• Treatment and provider options available in their geographic area or virtually • Internet access limitations (e.g., due to work environment, remote location) • Social influences of health (including socio-economic circumstances, race / class biases, proximity to healthy food outlets, care centers) • Obesity related disease burden (mobility limitations, complexity of care, access to / ability to manage care coordination)

Table 3: Key considerations in the customization of care delivery

Patients will be empowered to customize how care is delivered, and they will do so in partnership with their healthcare provider. Healthcare providers will be part of healthcare delivery systems that engage patients, supporting their identification, diagnosis and care. Healthcare providers will also support patients by building healthcare systems that can incorporate new evidence and update what works for patients with obesity, including the use of evidence-based telehealth and digital technologies. In other words, how a patient customizes their care delivery will be in partnership with, and influenced by, the institutional structure through which their care is delivered.

Obesity care delivery structures

With the aspects of care for people with obesity better understood and care options integrated, we must address how healthcare delivery structures can care for the high volume of patients in a timely manner and with consistent quality while also customizing the services, settings, and formats for clinically distinct subpopulations of patients, geographic availability of options, and the unique preferences of each person with obesity. Care capacity will remain a challenge for some time, as successful programs will attract more patients, forcing rapid expansion that may threaten quality. To address this high volume and customization challenge, the transformation of care practices outlined above must succeed in tandem, where the current three main models of obesity care delivery are prepared, coordinated, and structured to deliver current, non-biased, patient-customized care that can adapt to quality and monitoring standards as they develop. The three main models of obesity care delivery are: centers of excellence, PCP-centered care, and consumer-centered care delivery systems. Crucial to our ability to manage the quality and timeliness across a high volume of patients, these three main care delivery models must differentiate across patient populations, with the CoE model working with the most severe patients (Class 3 Obesity), the PCP-centered care model supporting patients designated Class 2 Obesity and the consumer-centered care model addressing the needs of patients in Class 1 Obesity (see ICD-10-CM E Code Classifications, above).

These main models must align with the advancements outlined above, including a more educated and sensitive process of patient engagement, identification and diagnosis. Each model will have different strengths in how they support shared capability building, but nonetheless, each must be

flexible to apply new metrics and integrate new standards of care as evidence develops. In addition to quality consistency and expanded, timely support, each model must be prepared to provide all aspects of integrated obesity care to their patient populations, staying current with standards of care, shifting care pathways as new evidence builds, and customizing care in partnership with their patients, including evidence-based telehealth and digital technologies. It will require substantial work to incorporate the multi-faceted improvements proposed in this roadmap into each model, but the expected transformation of obesity patient outcomes justify building upon the solid foundation of each current main model.

Obesity Centers of Excellence

Traditional Centers of Excellence (CoEs) are centrally located to provide access to many patients across a large geographic area. Primary care and subspecialty providers refer patients to such centers which include specialists that concentrate on patient care with the targeted conditions for patients with Class 3 obesity (i.e., BMI of 40 or greater) while serving all who seek their care. Similar to other disease areas, obesity centers of excellence could serve as a geographic center and be central in developing standards of care in obesity healthcare.

An obesity CoE will provide specialized care and access to standards of care in obesity care, while collaborating with other institutions to deliver the full validated treatments that obesity care requires. Most often, CoEs are part of a larger institution (e.g., a hospital) where they can have administrative scope to maintain a longitudinal database of their patients' complete obesity care experience. The evidence these institutions create will contribute to standards of care in the field and improve care delivery, perhaps with contractual support from payers. As their patients require, CoEs will likely integrate non-traditional service applications, such as telehealth appointments for care coordination and updates, or reporting mechanisms where patients log in to access aspects of the validated treatments. Importantly, the CoE would have the specialists and administrative support to review and advise on data from these reporting mechanisms.

Working with the patient population with the most severe obesity, the CoE model would likely require more in-person medical care at certain periods in a care pathway. Depending on the care pathway (e.g., bariatric surgery and its follow up treatment, coordination of medications across obesity –related diseases, etc.), CoE providers will play an important role in deciding how to customize delivery of services over the course of care (e.g. to include remote contact as effective along the more complicated points in the patient journey). Overall engagement from these patients would likely remain high, given the intensity of treatment needs.

Primary Care Provider (PCP) obesity care delivery

The second main model for obesity care emphasizes Primary Care Providers (PCPs), or more broadly, a patient's main medical provider who would work with patients with a Class 2 obesity severity designation (with BMI of 35 to less than 40). In this model, the PCP would be considered a trustworthy partner with whom a person with obesity could engage to develop a customized care plan through ongoing interactions. PCPs (and their staff) would:

- Develop a customized obesity care plan with each patient,
- Coordinate care services for each patient's needs,
- Work with external health insurance structures,

- Provide referrals to services not directly available within the PCP practice,
- Aid the patient in navigating the healthcare system (or directly coordinating the care plan and provider team), and
- Assess the quality and outcomes of services, including both validated treatments and customized delivery options, that their patients receive.

In this main model, PCPs would need the infrastructure (e.g., training, stable resources for intervention element supply, robust reimbursement coding) available to work successfully with patients with obesity and coordinate with other care providers. Given the current epidemic level of patient needs, the PCP model has an important role to play in obesity patient care thanks to its foundational presence in our healthcare systems. Yet to succeed, obesity bias and stigmas must be firmly irradicated at this first point of contact, and providers must have the resources and training to encourage patient engagement. PCPs may also benefit from digital and telehealth options and act as coordinators of the full, validated treatments, supported by regular patient check-ins. This PCP obesity care system would maintain a central role for medical expert oversight and coordination, including referrals to CoEs when needed, and continued health check-ups with these patients.

As people with obesity choose to engage with their PCP office, we expect they will be more proactive partners to share in decision-making, especially as PCP offices become more adept at managing obesity care without bias or stigma in their approach. Obesity severity Class 2 patients may have more flexibility to decide how their care is delivered, working with their PCP office to customize how they receive a full validated treatments that best align with their life circumstances.

Consumer-centric obesity care delivery

At the cusp of a radical change in care for patients with obesity, a consumer-centered care delivery model could provide greater scale, access to care and flexibility, with a less medicalized tone that may encourage some to seek and adhere to obesity care. We expect that the consumer-centered care delivery model will manage patients with a Class 1 Obesity severity score (with a BMI range from 30 to <35), delivering quality medical care while prioritizing patient convenience and shared-decision making in services to be accessed. While this model may prioritize patient convenience for care (e.g., using apps, telehealth appointments or other digitally based services), the model would benefit from being held to the same quality standards as other main models.[35]

Currently, consumer-centered programs have aligned across the validated treatment options of non-surgical services, from nutrition and exercise plans to patient support groups, and increasingly, obesity medications. The coordination of these services could serve as an early strength of this obesity care model, especially for those consumer-centered systems that align with accepted medical practices and engage board-certified specialists in their physician consultation programs. Consumer-centric programs have been working to incorporate telehealth and digital apps, where they now include medical telehealth appointments to support the broader service programs. This consumer-centric obesity care model will evolve to better coordinate with the other two models as well as adhere to, and perhaps support the development of, health quality standards and medical guidelines.

All patients with obesity will become more proactive to seek care as the bias and stigmas associated with obesity lessen. Patients at severity class 1 will be no less impacted by this shift to an

Box 3. Compounding medications

As a new generation of obesity medications has come to market, there have been supply shortages that disrupted availability of certain GLP-1 products. In such circumstances, the Food & Drug Administration (FDA) maintains a drug shortage list, actively monitoring drug availability to ensure that drug supply can meet patient demand. For medications on the drug shortage list, the FDA may waive some restrictions on compounding drugs that are "essentially copies" and so allow them to be introduced to the market until that time when the drug shortage has passed.[i]

Compounded medicines are not monitored, inspected or controlled to the same degree as FDA-approved medicines. Meant as a temporary measure, compounding companies are not held to the same rigors of manufacturing quality controls to which primary manufacturers of FDA-approved medicines are held responsible.[ii] Indeed, the National Association of Attorneys General petitioned the FDA to take action against compounding companies that are taking advantage of the high demand for approved GLP-1 medications. Signed by 38 Attorneys General, they urged the FDA to take action to address counterfeits, fake medications, illegal sales without prescriptions and compounding pharmacies that are producing adulterated copies of GLP-1s under insanitary conditions.[iii] The FDA declined to take immediate action, presumably due to the ongoing shortages, where doing so would harm patient access to initiate and maintain obesity therapy prescribed by a physician.

As of this writing, all GLP-1s have been taken off the FDA drug shortage list, meaning that the drug shortage has been resolved in each case and compounding pharmacies are thus supposed to stop selling their alternative products. The FDA regulations allow the compounding companies to operate for 60 days to dispense any orders they have received when the drug shortage has been resolved.[iv]

Some compounding pharmacies disagree that the GLP-1 product shortage has been resolved, particularly for some dosages not on the FDA labels of the reference products that nonetheless are prescribed by physicians. With their association, the Outsourcing Facilities Association (OFA) they are currently suing the FDA to allow continued GLP-1 compounding. They further argue that the compounding companies will lose their investment if no longer allowed to produce and sell their products.

Beyond a general lack of manufacturing and final product quality assurance, the FDA has limited oversight of adverse event reporting for compounded products. Compounders also do not provide FDA with evidence of their products' safety and efficacy.[v] At times of drug shortage crises when FDA- approved medications are not available, compounded medications can fill the gap with risks that the FDA evaluates are less than the benefits of increased patient access. However, when no manufacturing-based shortage of the FDA approved products exist, the added patient risks from compounded products "copies" are inappropriate and fall outside of clinical standards creating a two-tiered system of healthcare for people living with obesity.

CBSD programs embrace the need for, and the opportunities created by, data and evidence. Should evidence of patient efficacy or safety from alternative compounded doses, formulations, or active ingredient combinations be developed pathways for patient access and rewards for the developers should be available.

References

i. FDA. "Compounding when Drugs are on FDA's Durg Shortages List". FDA. https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list Accessed online 3/3/2025.
ii. In November 2020, the FDA's Cetner for Drug Evaluation and Research (CDER) Office of Compliance released it's guidance of Industry regarding "Insanitary Conditions at Compounding Facilities". https://www.fda.gov/media/124948/download Accessed online 2/26/2025.
iii. National Association of Attorney's General, letter to Acting FDA Commissioner, Sara Brenner, 2/19/2025. https://www.naag.org/press-releases/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/ Accessed 3/1/2025.
iv. Beaver, N.A. et al., GLP-1 Drugs: FDA Removes Lilly's Zepbound and Mounjaro (tiersepatide injection from its Drug Shortage List" in Health Care Law Today, posted 10/7/2024. FDA Ends Tirzepatide Shortage and Clarifies Compounding Restriction Accessed online 2/26/2025.
v. Hims. "Compounded Semagutide" hims website. https://www.hims.com/weight-loss/compounded-semaglutide Accessed on-line 3/3/2025. Note in particular their footnote: "FDA does not evaluate compounded products for safety, effectiveness, or quality."

assumption of obesity as a disease. Patient who seek care through these systems may not have severe complications or obesity-related conditions, but they will still require support and advice in the diagnosis and treatment of this disease. These patients will also require access to the full array of validated treatments, customizing the delivery of that care to best suit their life circumstances. These patients will benefit from coordination support to engage, monitor compliance, and ultimately reach positive health outcomes.

Action Components of 3C) Customized delivery

Develop Artificial Intelligence (AI) programs to coordinate all services including booking of services and appointments, monitoring of engagement with validated services (e.g., meetings attended, hours of sleep daily, physical exercise tracking, weight measurements & etc.).

- Feedback to healthcare professionals in each of the care delivery systems must be built into the services so that care will be responsibly measured and monitored for quality assessment purposes. These metrics could then inform standards of care on a systems-wide level.
- AI programs could also support healthcare delivery systems to share patient data and facilitate the use of care coordination programs where data has been collected, and evidence is available to measure and compare their success.

Integrate digital services that support customized access to resources where an app can help with meal planning, linked to a shopping service that can deliver foods based on the meal plan.

Build evidence from customized delivery services into communication and education programs so that shared decision-making practices are taught that foster patients' resilience and engagement in the patient journey. Continue to investigate and report accessibility constraints, investing in solutions.

Identify sub-populations that remain outside healthcare settings: In ongoing experiments to develop feasible care journeys that incorporate customized delivery options, there is an opportunity to identify why some people with obesity do not engage in healthcare solutions. For example, more women than men engage health services for obesity care, and there are signs that a subpopulation with high clinical need exists that are not seeking care. Investigating why would be a first step toward proactive engagement in obesity care.

Obesity roadmap architecture: solution areas, elements, and action components

Table 4 – Table 6 capture the specific details that link our three solution areas, broken down into key solution elements and finally action components that allow us to move from elucidation of the challenges at hand to concrete recommendations on what to change, and how. Multiple stakeholders, multiple leaders will be required to effect these changes. It is our hope that we have contrib-

uted clarity to the theories for change, and a roadmap to get it accomplished that will serve many who will continue to effect systemic changes in the dialogue, the diagnosis, and the care pathways for people with obesity.

Patient identification, engagement, and diagnosis

Solution Elements	Action Components
A comprehensive, public communications program	Message content that is tailored to specific audiences, utilizing evidence-based information
	Breadth & Depth of Message Penetration: Disseminate across multiple platforms simultaneously for a deep penetration that would generate a paradigm shift in our assumptions about obesity and its care
	Apply measures of success on the communications program
Build more comprehensive obesity education for care providers across healthcare systems	Build obesity identification and care into medical, nursing and pharmacy school curriculum. Include obesity training in licensure tests
	Implement obesity care coordination training programs at nursing schools
	Create mandatory Continuous Medical Education (CME) training programs for the disease and care of obesity
	Educate health systems on federal accessibility and equipment requirements to provide care for people living with obesity
Normalize patient outreach processes to initiate medical treatment for obesity care	Identify and engage new patients
	Consistent documentation of people with obesity by each HCP
	Create a pre-appointment checklist
	Develop patient information materials that outline obesity as a disease and obesity care options

Table 4: Solution elements and action components for patient identification, engagement, and diagnosis

Shared capability building

Solution Elements	Action Components
Metrics development	Integrate training around obesity-related coding and billing procedures in medical education programs
	Build improved and non-biased obesity coding system
	Engage all Coding and Coding assessment agencies to coordinate their updates to codes for obesity
	Identify and coordinate the diversity of coding and metric innovations that are under development to navigate the pool of information available beyond BMI assessments and pool the information to accommodate best use of evidence for patients, providers and payers
Quality and Outcomes Monitoring	Develop a strategic set of peer-review articles that bring attention to the current state of coding and quality measures
	Build partnerships across scientific agencies and institutions focused on obesity care improvements
	Create NCQA behavioral health awards that recognize quality obesity care programs
	Partner to develop an NCQA- sponsored Innovation Summit focused on Obesity
Data collection & Evidence Generation	Embrace the current chaos: With evidence-based dialogues, clarify specific data and analysis that is needed to a) move to clarity about the differentiating factors that determine disease severity; b) convey to patients what illnesses threaten their health, based on their specific disease profile
	Encourage development of an aggregator marketplace to produce outcomes-based evidence
	Establish bridges across public-private partnerships to collect and share data across institutional boundaries
	Create evidence generation and evidence-sharing channels that allow health systems infrastructure to be updated more quickly (e.g., clinical guidelines, coding for reimbursement and clinician education programs)
	Plan for data collected to meet requirements at different levels of sophistication
	Include patient-reported outcomes in data collection processes

Solution Elements	Action Components
Align incentives across stakeholders	Stakeholders must continue to experiment, designing programs that improve health outcomes
	Share research/outcomes from private contracts
	Build a resource navigation tool to share information and decision tools

Table 5: Solution elements and action components for Shared Capability Building

Integrated care

Solution Elements	Action Components
Validated Treatments	Share research results that assess ancillary services' use and effectiveness
	Publish a quality review of telehealth and digital technology (e.g., apps) that support customized delivery of obesity care while maintaining care quality
Evidence-based care path development	Build patient journeys for obesity sub-populations that are based on analysis of successful utilization of the full, validated treatments and are structured to respond flexibly to new evidence
	Work with relevant medical societies and patient associations to establish regular and timely updates to standards of care, inconsideration of new evidence
Customized delivery	Develop Artificial Intelligence (AI) programs to coordinate all services
	Integrate digital services that support customized access to resources
	Build evidence from customized delivery into communication and education programs
	Identify sub-populations that remain outside healthcare settings

Table 6: Solution elements and action components for Integrated Care

Applying the roadmap architecture in practice

Long-lasting, systemic change is not the purview of large, Federal health systems alone. All potential patients for obesity care cannot be reached unless specific programs, including those for managed populations, are able to implement the solution area, elements and action components for their own patient populations. Table 7 provides a snapshot of example "micro applications" of the Obesity care roadmap to real communities; to patient groups and subgroups that are unified within a healthcare system and are willing and able to embrace the medical system where healthcare solutions for the disease of obesity can be managed.

Each of the organizations highlighted below have embraced a comprehensive approach to obesity care while customizing their program for their context. While no one program follows the Roadmap exactly, each program seeks to identify patients and appropriately encourage diagnosis and care for people with obesity. Each of these programs also seeks to use metrics and track quality of care and patient outcomes. Each program is generating data that will shape contracts and generate payments for results as well as further our knowledge and understanding of how obesity care can improve. Finally, the patients in these programs are provided a full set of validated treatment options with care pathways shaped by evidence. These programs also encourage patients to work with their HCPs to customize how they receive care including by apps and remote monitoring devices.

These example programs in great part embraced most of the solution elements outlined in this Obesity Roadmap. There are some solution elements that to date have not been included in all the examples, such as comprehensive communication programs or broad HCP education programs. Given the proscribed patient populations and provider groups involved in these programs, it is reasonable to think that these more comprehensive agendas would not be central to the initial efforts. However, as outlined above, comprehensive communication and education programs require cross-functional and cross-institutional strategies to fully effect these necessary changes. At the same time, many solution elements appear fundamental to these programs' success including that they have: experimented with outcomes measures to monitor patient success and tracked data over time. While still early for some of these programs, the interest in tracking outcomes and revising programs based on this evidence is an important progression in obesity care and management.

Solution Element	AT&T (Examplar of employer plan)	Regional health plan Examplar	Obesity Center of Excellence Examplar
A comprehensive, public communications program	None, introduced at prescription filling	Press releases, social media posts, reposts by other organizations, direct mailings, newsletters, Sales and Marketing presentations, case manager engagement	N/A

Solution Element	AT&T (Examplar of employer plan)	Regional health plan Examplar	Obesity Center of Excellence Examplar
Comprehensive obesity education for care providers across healthcare systems	None	None	Specialized/ dedicated team that understands obesity; can create provider network and ensure credentialing
Normalized patient outreach processes to initiate medical treatment for obesity care	Post-script outreach	Direct mailings and personal outreach for initial and long-term obesity care	None
Metrics development	Utilization (enrollment, adherence), Net Promoter Score (user experience), Work Limitations Questionnaire (impact on productivity), Weight reduction	Member engagement, demographics, avg BMI, comorbid conditions, disease-specific metrics, Net Promoter Score	Measures for sustainable weight loss incorporated into care plans
Quality and Outcomes Monitoring	Outcomes measured at 6 months and 12 months; with outcomes-based payments to providers triggered every month. Individual-level payments also supported based on reaching established goals	On Qrtly basis and in addition to above metrics, change in BMI, change in weight, % achieving ≥ 5% wt loss, % maintaining ≥ 5% wt loss, % achieving ≥ 10% wt loss, % maintaining ≥ 10% wt loss, % achieving ≥ 15% wt loss, % maintaining ≥ 15% wt loss. For employer groups, % engaged, % with weight loss, avg % wt loss, A1C tracking, BP tracking, etc). Goal tracking for patient self-use (app/ website).	Tracked over the performance period
Data collection & Evidence Generation	Claims, demographics, lab values, mobile app interaction, including PROMs, weight monitoring, BP via integrated scales and monitors.,	Rx claims data, coach and patient reported data, Wt, BP, A1C with integrated scales and monitors	Can set up data-sharing pipelines and business agreements with employers, TPAs, providers, PBMs.
Align incentives across stakeholders	Provider outcomes-based payments at a patient level	Incentives between provider and the payer	COE can offer various financial structures based on risk sharing capacity and partner's preferences. COE can contract with employer, PBM, insurance.

Solution Element	AT&T (Examplar of employer plan)	Regional health plan Examplar	Obesity Center of Excellence Examplar
Validated Treatments	Diverse set of options	Nutrition-focused but with personalized lifestyle coaching, educational opportunities, engaging and motivating challenges	Comprehensive care with lifestyle support and pharmaceutical & procedural interventions
Evidence-based care path development	Appropriate treatment in relation to obesity staging model	Program supports first-line and long-term obesity care	Incorporates obesity treatment protocols
Customized delivery	Patient-specific determination by specialist; Patient supported by medical and behavioral team; Educate patients on the validated treatments; Mobile app	Patient-tailored guidance by dietitians and coaches; Additional tracking, support and learning opportunities through app	Coordinates care with primary and specialty providers

Table 7: Applying the Roadmap Architecture to three examples in the real world

In each aspect of the Roadmap, we have sought to identify those solution areas that hinder obesity care and management and then clarify how to go about eradicating these limitations. From the three solution areas and their solution elements, and then to more concrete action components, the Roadmap for Transforming Obesity Disease Management encourages paradigmatic change to fully treat obesity as a chronic disease. The example obesity care programs in Table 7 have begun breaking down the bias and stigma amongst their patient populations, providers, and communities. They are providing care to their populations that normalizes care for these groups. As these programs progress, and share information about their strengths and weaknesses externally, we are confident that their successes will continue to mirror the Roadmap for Transforming Obesity Disease Management.

For more downloadable Roadmap resources, such as the infographic and action checklist, visit newdigs.tuftsmedicalcenter.org/obesity

About the Center for Biomedical System Design

The Center for Biomedical System Design in the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center is dedicated to improving health outcomes by accelerating appropriate and timely access for patients to biomedical products, in ways that work for all stakeholders. The Center designs, evaluates, and catalyzes the real-world implementation of system innovations that are too complex and cross-cutting to be addressed by a single organization or market sector. Its members include global leaders from patient advocacy, payer organizations, biopharmaceutical companies, regulatory agencies, clinical care, academic research, and investment firms. https://newdigs.tuftsmedicalcenter.org.

References

1. We have set specific key assumptions that imply that coverage challenges will have been met so that this work does not maintain a focus on coverage and reimbursement rates. There is excellent work on these issues, including The Institute for Clinical and Economic Review (ICER) white paper: Pearson, S et. Al, "Affordable Access to GLP-1 Obesity Medications: Strategies to Guide Market Action and Policy Solutions" April 9, 2025. White paper downloaded 5/5/2025: https://icer.org/wp-content/uploads/2025/04/Affordable-Access-to-GLP-1-Obesity-Medications-_-ICER-White-Paper-_-04.09.2025.pdf
2. In the process of our investigations, the NEWDIGS consortium built on excellent work in obesity patient care, especially work on the journey for patients with obesity. See specifically the American Association of Clinical Endocrinology (AACE) journey for patients with obesity: https://www.aace.com/files/obesity-patient-journey-oct-2024.pdf
3. We have set specific key assumptions that imply that coverage challenges will have been met so that this work does not maintain a focus on coverage and reimbursement rates. There is excellent work on these issues, including The Institute for Clinical and Economic Review (ICER) white paper: Pearson, S et. Al, "Affordable Access to GLP-1 Obesity Medications: Strategies to Guide Market Action and Policy Solutions" April 9, 2025. White paper downloaded 5/5/2025: https://icer.org/wp-content/uploads/2025/04/Affordable-Access-to-GLP-1-Obesity-Medications-_-ICER-White-Paper-_-04.09.2025.pdf
4. In the September 2024 Design Lab and the subsequent summary report, the consortium had recommended 4 solution areas. The fourth solution area, "Obesity care delivery structures" has been subsumed in the Integrated care solution area. This solution area is no less important, but the delivery structures and how they might work together were out of scope for the April 2025 Design Lab
5. Stigma and bias keep people from seeking and keep healthcare providers from engaging with people about obesity. These are fundamental challenges to managing obesity as a disease. Bias and stigma do not stop there, unfortunately; these attitudes and ideas limit the progress across shared capability-building and the long-term development of integrated care practices for people with obesity. Dietz WH, Solomon LS, Pronk N, Ziegenhorn SK, Standish M, Longjohn MM, Fukuzawa DD, Eneli IU, Loy L, Muth ND, Sanchez EJ, Bogard J, Bradley DW. An Integrated Framework For The Prevention And Treatment Of Obesity And Its Related Chronic Diseases. Health Aff (Millwood). 2015 Sep;34(9):1456-63. doi: 10.1377/hlthaff.2015.0371. PMID: 26355046. See also Le Jemtel TH, Samson R, Oparil S. Integrated Care Model of Adiposity-Related Chronic Diseases. Curr Hypertens Rep. 2022 Nov;24(11):563-570. doi: 10.1007/s11906-022-01223-3. Epub 2022 Sep 9. PMID: 36083439.
6. Stokes, A. Collins, J.M. Grant, B.F. Hsiao, C. Johnston, S.S. Ammann, E.M. Berry, K. M. Tong, C., and Scamuffa, R.F.(2018). Prevalence and Determinants of Engagement with Obesity Care in the United States. Obesity, 26(5), 814-818. https://doi.org/10.1002/oby.22173.
7. "…fewer than 5% of eligible individuals are treated with [behavioral, pharmacological, and surgical treatment for obesity]" Quoted from Weight Can't Wait: Guide for the management of Obesity in the Primary Care Setting", STOP Obesity Alliance, October 2020, p. 3. Weight Can't Wait | STOP Obesity Alliance | Milken Institute School of Public Health | The George Washington University
8. The Lancet Diabetes & Endocrinology Commission released a report in January 2025 that outlines concerns about obesity as a disease, but also recognized that stigma leads to delays in seeking medical care. Published Online January 14, 2025 DOI: 10.1016/S2213-8587(24)00316-4 p15.
9. In 2020, Nature Medicine published a "joint international consensus statement for ending stigma of obesity" Joint international consensus statement for ending stigma of obesity | Nature Medicine. They argued that "Challenging and changing widespread deep-rooted beliefs, longstanding preconceptions, and prevailing mindsets requires a new public narrative of obesity that is coherent with modern scientific knowledge." P. 486.
10. "Provider Competencies for the Prevention and Management of Obesity" June 2017. https://www.obesitycompetencies.gwu.edu/competencies Accessed online on 3/8/2025.
11. Our recommendation includes a stronger role for primary care physicians and their staff to support people with obesity. Healthcare provider education remains a necessary solution to obesity care, but we must acknowledge that the USA is seeing a continued mild decline in the PCP workforce, with 103.8 primary care clinicians and 67 primary care physicians per 100,000 population (2022). See: Milbank Memorial Fund report, 'The Health of US Primary Care: 2025 Scorecard Report – The Cost of Neglect: How Chronic Underinvestment in Primary Care is Failing US Patients'.
12. Butsch WS, Kushner RF, Alford S, Smolarz BG. Low priority of obesity education leads to lack of medical students' preparedness to effectively treat patients with obesity: results from the U.S. medical school obesity education curriculum benchmark study. BMC Med Educ. 2020 Jan 28;20(1):23. doi: 10.1186/s12909-020-1925-z. PMID: 31992274; PMCID: PMC6988262. The Obesity Medicines Education Collaborative (OMEC) has organized a 12-part education series, but as this article explains, medical schools are not confident that their students have sufficient knowledge of obesity.
13. It is widely agreed that the culture of care-how HCPs approach people with obesity—must improve. At the same time, the current solo use of BMI as the diagnostic assessment is problematic. Joining many professionals, the Lancet Diabetes & Endocrinology Commission encouraged the use of alternative measures (e.g. waist circumference or body fat percentage) to confirm excess adiposity, noting that "BMI provides no information about the functional status of tissues and organs, or the ability of an individual to conduct normal daily activities…" DOI: 10.1016/S2213-8587(24)00316-4 p.13.
14. The STOP Obesity Alliance included a pre appointment check list in their 2022 Weight Can't Wait guide. This guide is a good start for preparations for an initial conversation, and could be used to build a regular process of pre-appointment information sharing. See https://stoppublichealth9.drupal.gwu.edu/sites/g/files/zaxdzs4356/files/2022-02/wcw-encounter-flow.pdf.
15. See Avalere White Paper, "Barriers to Obesity Care: Diagnostic Coding, Medical Billing, and Reimbursement," https://avalere.com/wp-content/uploads/2022/12/obesity_care_barriers_white_paper.pdf. Dec. 2022, pp. 7-10. Accessed 2/16/2025.
16. HCPs seem to get around the reimbursement issue by diagnosing obesity related disease as the primary diagnosis. While helpful to some degree, without a diagnosis of obesity, it is unlikely that a patient will receive the full panoply of treatments for obesity, which may negatively impact health outcomes. Ibid., p. 6.
17. Ibid, p10.
18. See also the Lancet Diabetes & Endocrinology Commission report, where the limitations of BMI and anthropometric measures are discussed. Published online January 14, 2025. Definition and diag-

nostic criteria of clinical obesity - The Lancet Diabetes & Endocrinology

19. Not listed here is the patient perspective. In our future state, we expect that coding updates will have incorporated important guidance from obesity experts as they develop everything from clinical guidelines to standards of care. To ensure pervasive inclusion of the patient perspective, patients should be included in the design and analysis of the evidence, participate as decision makers in the development of the clinical guidelines, and be included in the assessment of those guidelines' implementation in obesity care practice.
20. Zvenyach, T., Dietz, W.H., "Quality Measurement Gaps and Future Directions in the Assessment of Obesity"in Current Obesity Report (2023)12:474-481. See Quality Measurement Gaps and Future Directions in the Assessment of Obesity. Accessed online 3/9/2025.
21. Ibid. Please also see the International Consortium for Health Outcomes Measurement (ICHOM) website: Adult Obesity — ICHOM. Accessed 2/13/2025.
22. See https://norccentral.org/
23. At the time of this writing, it is unclear how the cuts to publicly funded research and development will impact these institutions, or the research they are doing that might impact obesity care and its development.
24. The sub team also discussed how either research could be shared, or data analyzed, by Artificial Intelligence programs designed to fit the purpose. AI may well allow for economies of scale in data generation and/or communication opportunities. More discussion is needed as this field continues to develop.
25. The January 2025 Lancet Commission contends that "because the illness directly caused by obesity is yet to be defined, obesity lacks a precise clinical identity" p. 2. Published online January 14, 2025. Definition and diagnostic criteria of clinical obesity - The Lancet Diabetes & Endocrinology The discussion continues.
26. Lopez, C., Bendix, J. and Sagynbekov, K., "Weighing Down America: 2020 Update, A community approach against Obesity" Milken Institute, 2020, p.1.
27. Sexton Ward, A. et. Al. "Benefits of Medicare Coverage for Weight Loss Drugs," Schaeffer Center White Paper Series, April 2023. P. 1.
28. Hernandez I, Sullivan SD. Net prices of new antiobesity medications. Obesity (Silver Spring). 2024 Mar;32(3):472-475. doi: 10.1002/oby.23973. Epub 2024 Jan 16. PMID: 38228492.
29. Sexton Ward, A. et. Al. "Benefits of Medicare Coverage for Weight Loss Drugs," Schaeffer Center White Paper Series, April 2023.
30. One important way to stabilize the patient population is to have consistent documentation of disease. HCPs, especially those that are part of a subscription model must be encouraged to document patients using current ICD-10 codes.
31. The Institute for Clinical and Economic Review (ICER) has noted that "evidence-based guidance on which lifestyle and weight management programs are most effective in complementing GLP-1 drugs is lacking". See Pearson, S et. Al, "Affordable Access to GLP-1 Obesity Medications: Strategies to Guide Market Action and Policy Solutions" April 9, 2025, p. 9. White paper downloaded 5/5/2025: https://icer.org/wp-content/uploads/2025/04/Affordable-Access-to-GLP-1-Obesity-Medications-_-ICER-White-Paper-_-04.09.2025.pdf
32. Lazarus, E. and S. Ortiz-Pujois. "Increasing clinical awareness of obesity as a serious, chronic, relapsing and treatable disease" Am J Manag Care.2022:28:S271-S278.
33. U.S. Food and Drug Administration. FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014. Published June 04, 2021. Accessed online 2/16/2025. https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014?os=av...VdmGCEzR&ref=app
34. BMI alone is currently being used to diagnose obesity. However, the limitations of BMI as the determinant of a diagnosis—even in terms of severity of disease—is a central point of concern in the Lancet Diabetes & Endocrinology Commission report. The report recommends using BMI in concert with a second assessment of anthropometric measures or biomarker testing. However, there is no one definitive diagnostic tool that is currently available to replace BMI. The recent ICD-10-CM codes reflect these circumstances. Lancet Diabetes & Endocrinology Commission report. Published online January 14, 2025. https://www.thelancet.com/journals/landia/article/PIIS2213-8587(24)00316-4/abstract (page 18).
35. Consumer-centered care delivery systems continue to develop. ICER's recent White Paper identifies "carve-out obesity management programs" where insurers will partner with a third party to provide a full array of obesity care management treatment and services. These programs are new enough that there is little data available to assess their level of care quality or patient outcomes. See Pearson, S et. Al, "Affordable Access to GLP-1 Obesity Medications: Strategies to Guide Market Action and Policy Solutions" April 9, 2025, p. 33-34. White paper downloaded 5/5/2025: https://icer.org/wp-content/uploads/2025/04/Affordable-Access-to-GLP-1-Obesity-Medications-_-ICER-White-Paper-_-04.09.2025.pdf