

Planned Evaluation of the Healthy Weight Clinic Pediatric Weight Management and Implementation: Massachusetts-CORD 3.0

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Abstract

Background: Despite evidence that offering multidisciplinary treatment for children with obesity is effective, access to evidence-based pediatric weight management interventions (PWMI) is limited. The *Healthy Weight Clinic* PWMI is a multidisciplinary approach in primary care that improves BMI among children with a BMI \geq 85th percentile.

Objective: To describe the method by which we will evaluate the adoption, acceptability, and feasibility of integrating and implementing a multidisciplinary *Healthy Weight Clinic* (HWC) into primary care.

Design/Methods: We used the Consolidated Framework for Implementation Research (CFIR) domains and constructs to inform our implementation strategies. We will use a Type III hybrid effectiveness-implementation design to test our implementation strategies and improvement in BMI. Sources of data collection will include qualitative interviews with patient caregivers, HWC staff and surveys with HWC staff, patient caregivers, and electronic health record data. Our outcomes are guided by the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework.

Results: We identified all five CFIR domains as integral for successful implementation. Some strategies to address barriers within these domains include online self-paced training modules for the HWC staff, a virtual learning collaborative, and engagement of site leadership. Outcomes will be measured at the patient and pilot site levels, and they will include patients reached, patient health outcomes such as BMI and quality of life, level of adoption, acceptability, feasibility, and sustainability of the PWMI.

Conclusion: Our use of implementation science frameworks in the planning of *Healthy Weight Clinic* PWMI could create a sustainable and effective program for dissemination.

Keywords: childhood obesity; implementation; primary care

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Introduction

The prevalence of childhood obesity among children and adolescents in the United States is estimated to be 18.5% and has been increasing over the past 15 years despite multiple public health efforts.¹ Severe obesity, defined as a BMI greater or equal than 120% of the 95th percentile for age and sex, has also been increasing in some subgroups.² Childhood obesity disproportionately affects low-income³ and communities of color,¹ highlighting the need for effective dissemination of pediatric weight management interventions (PWMIs) that can reach all affected populations, adapt to the circumstances of each community, and be sustained in the long term.

The *Healthy Weight Clinic* PWMI, built from key components of the effective and evidence-based PWMIs *Connect for Health*,⁴ *Mass in Motion*,⁵ and *Clinic and Community Approaches to Healthy Weight*,⁶ is designed for delivery in primary care settings. An implementation package to support spread and adoption of the *Healthy Weight Clinic* PWMI is being developed and tested through the CDC-funded Childhood Obesity Research Demonstration Project. The package will include clinician-facing tools embedded into the electronic health record (EHR), a primary care based *Healthy Weight Clinic* (HWC), staff training resources, as well as patient and caregiver-facing educational materials and community resource guides customized by each HWC team. It will be piloted at two federally qualified health centers in rural Mississippi by using a Type III hybrid effectiveness-implementation design. The elements of the package are described in a separate article in this supplement in greater detail.⁷ The Type III hybrid effectiveness-implementation design was selected for this project given the primary focus on implementation of the evidence-supported PWMI. Type III designs aim first at understanding and describing the implementation processes and outcomes, with the secondary aim of demonstrating the effectiveness of the intervention on meaningfully changing the target child and family outcomes evaluated in prior efficacy and effectiveness trials.⁸

The use of implementation science has grown in recent years, with an overarching aim of translating evidence-based interventions such as the *Healthy Weight Clinic* PWMI into practice. Many theories, frameworks, and models have been developed and can be used across different stages of implementation to describe and enhance the success of the intervention.⁹ More systematic use of these during implementation efforts is also expected to help increase the comparability of studies and the production of generalizable knowledge that could result in wider dissemination.^{10,11} This study uses two complementary models and frameworks. The Consolidated Framework for Implementation Research (CFIR)¹² was developed to consolidate published implementation theories into a comprehensive framework that would aid researchers in describing and evaluating multi-level implementation determinants throughout relevant stages of implementation. Its constructs are organized into

five domains: intervention characteristics, inner setting, outer setting, characteristics of individuals, and process.¹² The CFIR has been used in the evaluation of weight management programs for children and adults,^{13–18} but a smaller number of these have been conducted within the context of structured weight management interventions in the health care system.^{14,16,18} We aim at extending the literature by using this comprehensive determinant framework to inform our implementation strategies for the *Healthy Weight Clinic* PWMI.

We will evaluate implementation outcomes according to the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework. RE-AIM consists of the following five dimensions: reach, effectiveness, adoption, implementation, and maintenance.¹⁹ The Implementation dimension encompasses fidelity along with acceptability, appropriateness, and feasibility. Consistent with contemporary application of the RE-AIM framework, we will use it in the evaluation of our pilot phase of *Healthy Weight Clinic* PWMI^{20,21} and also apply our learnings directly to the next iteration of the PWMI in a planning manner.²⁰ Previous applications of RE-AIM in PWMIs have demonstrated barriers that commonly prevent proper translation of research interventions into practice.^{20,21} Further, to evaluate implementation and effectiveness we will apply the RE-AIM framework in its entirety.²² We hypothesize that its incorporation into our model for the *Healthy Weight Clinic* PWMI will ensure rigorous evaluation of the specific implementation strategies chosen. This evaluation is furthered by the use of the Implementation Research Logic Model,²³ which we will use to specify the hypothesized conceptual and causal relationships between specific implementation strategies and implementation outcomes (see Fiechtner et al., this issue). This will further inform the development of the final iteration of the *Healthy Weight Clinic* PWMI to ensure desired impact when disseminated at scale.

In this article, we describe our implementation strategies for *Healthy Weight Clinic* PWMI, in the context of the CFIR determinant framework, as well as our plans for evaluating implementation outcomes by using the RE-AIM framework.

Determinants: Describing the Implementation Context

The CFIR has been used across a range of disciplines in the implementation preparation stage to modify the planned implementation strategies and adapt the intervention.²⁴ We met as a research team on multiple occasions to develop our Implementation Research Logic Model. Our research team consists of staff members of the American Academy of Pediatrics (AAP) Institute for Healthy Childhood Weight, a local Mississippi pediatric provider leader, past implementers of *Mass in Motion Healthy Weight Clinics* and *Clinic and Community Approaches to Healthy Weight*, an implementation scientist with expertise in PWMIs, and pediatric obesity researchers. Throughout

Table 1. Consolidated Framework for Implementation Research Constructs and Implementation Strategies for Healthy Weight Clinic Pediatric Weight Management Intervention

CFIR domains	CFIR constructs	Implementation strategies
Intervention characteristics	Intervention source ⁺² Relative advantage ⁺² Evidence strength and quality ⁺² Competing demands ⁻¹ Evidence-based + I Appropriate in primary care ⁺² Adaptability ⁻¹ Complexity ⁻¹ Design quality and packaging ⁺¹	Online provider training modules, provider virtual learning collaborative, engaging health center leadership, ongoing meetings, identify and form new clinical teams, clinician reminders (BMI alerts, labs, counseling, referrals)
Inner setting	Structural characteristics ⁺¹ Networks and communications ⁺¹ Readiness for implementation <ul style="list-style-type: none"> • Leadership engagement⁺² • Available resources⁺¹ Implementation climate <ul style="list-style-type: none"> • Tension for change⁺¹ • Compatibility⁺¹ • Tangible fit⁺² • Alignment⁺¹ • Workflow⁻¹ • Learning climate⁺¹ 	Engaging health center leadership, quality improvement, identify and form new clinical teams, clinician reminders (BMI alerts, labs, counseling, referrals)
Outer setting	Patient needs and resources ⁻² Cosmopolitanism ^{0/-1} External policy and incentives ⁺¹	Virtual learning collaborative, community resources engagement (capturing local knowledge), engaging external state-level and national organizations, utilize financial strategies, addressing social determinants of health
Characteristics of individuals	Knowledge and beliefs about intervention ⁺¹ Self-efficacy ⁺¹ Training ⁺²	Online provider training modules, provider virtual learning collaborative, ongoing meetings, fidelity monitoring with quarterly checklist, utilize financial strategies, quality improvement, identify and form new clinical teams
Process	Engaging ⁺¹ Opinion leaders ⁺² Champions ⁺² Planning ⁺¹ External change agents ⁺² Reflecting and evaluating ⁺¹	Training modules, engaging health center leadership, engaging external state-level and national organizations, ongoing meetings, fidelity monitoring with quarterly checklist, data monitoring and feedback, quality improvement

Superscript numbers denote relative strength of the determinant.

CFIR, Consolidated Framework for Implementation Research.

the development of our Implementation Research Logic Model (please see Fiechtner et al. in this issue), constructs within each of the five CFIR domains were identified by the team (Table 1). Each construct was then given a group-consensus rating based on the coding system of Damschroder and Lowery¹⁴ to gauge the relative strength of the determinant on the following scale: -2 (*strong negative impact*), -1 (*weak negative impact*), 0 (*neutral or mixed influence*), 1 (*weak positive impact*), and 2 (*strong positive impact*).

Intervention Characteristics

The *Healthy Weight Clinic* PWMI is a longitudinal, team-based intervention housed in primary care with the external support and resources in the form of a package that includes resources and training. It includes evidence-based core components from the *Connect for Health*,⁴ *Mass in Motion*,⁵

and *Clinic and Community Approaches to Healthy Weight*⁶ trials, all of which were implemented in primary care. The intervention source is external to the community health centers (created by Dr. Taveras' team), which provides the intervention design and the evidence base as a relative advantage for implementation in each community health center. The engagement of key stakeholders, such as health center leadership, during exploration to sustainment stages will inform adaptation to this program in a sustainable manner and minimize competing demands of clinical staff, which can act as facilitators for implementation.

Inner Setting

Structural characteristics of the community health centers, such as their onsite physical activity facilities, internal nutritionists/dietitians, and previous implementation of

other adults and PWMIs, are considered facilitators for implementation. By identifying new clinical teams and increasing skill set and self-efficacy through the package's training and support, we aim at supporting multidisciplinary communication that can improve clinical care and adoption of the program. Frequent collaboration with health center leadership and clinical staff has informed our knowledge about the implementation climate at the site. Identifying the health center's tension for change (degree to which stakeholders perceive their current situation as intolerable), learning climate (individuals feel psychologically safe to try new methods and there is sufficient time and space for reflective thinking and evaluation), and compatibility (tangible fit and alignment) can serve to promote the implementation of *Healthy Weight Clinic* PWMI and minimize a potential negative effect from proposed changes in workflow due to competing demands. Moreover, this collaboration with health center leadership helps identify available resources and enhances readiness for implementation.

Outer Setting

Children with overweight and obesity are also more likely to suffer from unmet social needs, which can decrease their ability to make and sustain lifestyle changes. To support patient needs, we will work to identify and leverage community resources that patients can access to mitigate unmet social needs. As in our past work, we will work with the health centers to create a tailored community resource guide utilizing known categories of resources that have aided patients in our effectiveness trials.²⁵ Cosmopolitanism, defined as the connectedness of a health center to outside organizations, is expected to be variable across health centers, and depending on each health center's circumstances, could function as a barrier or neutral determinant for implementation. We suspect that health centers that are well connected to community-based organizations and can provide resources for their patient population may be more effective than those that do not have the networks predetermined before implementation. In an effort to potentially mitigate this barrier, we plan to incorporate a virtual learning community among all participating health centers in an effort to provide extra support and brainstorm opportunities for external connections. In addition, we are actively engaging in unstructured interviews, with external state and national-level organizations that can aid in reimbursement to allow for program sustainability through supportive policies and incentives.

Characteristics of Individuals

The *Healthy Weight Clinic* PWMI virtual asynchronous training modules for the HWC staff will serve to augment the individual clinical staff knowledge and beliefs about the intervention. A virtual learning collaborative, technical assistance, quality improvement, and support from local and previous implementation champions will facilitate the trialing and adoption of provided tools or resources, build

skills, and improve self-efficacy. Additional strategies include fidelity monitoring to ensure care is provided in a cultural and weight-sensitive manner, and utilization of financial strategies (making billing easier for providers).

Process

Throughout each stage of the process of implementation, the continuous involvement of health center leadership and champions in ongoing meetings is paramount for planning and addressing barriers as they arise. External state and national-level organization engagement is expected to contribute to ensuring the process of implementation leads to a sustainable and generalizable program. For reflection and evaluation, the team will utilize fidelity monitoring, data monitoring and feedback, and quality improvement methods.

Assessment of Implementation Outcomes: RE-AIM

We will use the RE-AIM framework to evaluate implementation. The results of these outcomes at our pilot community health centers will help inform the final PWMI package and determine what aspects of the evaluation plan should be incorporated when disseminating more broadly. Table 2 highlights the proposed operationalization of the RE-AIM outcomes, how they will be measured, and the level of analysis.

Reach

For the purposes of this study, we defined reach as the proportion of the target population that enroll in the *Healthy Weight Clinic* PWMI. To evaluate this in the pilot phase, we will measure the referrals made to the HWC and those enrolled out of the community health center's total eligible children aged 2–18 with a BMI \geq 85th percentile. These measures will be pulled directly from the health center's EHR system.

Effectiveness

Measures of effectiveness will be analyzed at the patient ("individual") level. As mentioned in Table 2, these consist of health outcomes [*i.e.*, BMI (from EHR please see Fiechtner et al. in this issue for more details), Quality of Life,²⁶ Binge Eating,^{27,28} Stress,²⁹ *etc.* from caregiver surveys], as well as patient and caregivers' acceptability and satisfaction (from caregiver surveys and qualitative interviews), and attendance adherence to the PWMI (from administrative data).

Adoption

Adoption will be measured at the community health center level. Use of training components and package elements will be measured at the intervention delivery staff (provider, nutritionist/dietitian, community health worker) level on the online training platform. We will monitor staff attending the virtual learning community and will also observe package components used during the quarterly fidelity monitoring.

Table 2. Reach Effectiveness Adoption Implementation Maintenance Outcomes for the *Healthy Weight Clinic* Pediatric Weight Management Intervention

Construct/level of analysis	Outcome	Measure source
Reach/health center (practice)	<i>Healthy Weight Clinic</i> Referrals <i>Healthy Weight Clinic</i> Enrollment Message Campaign Enrollment	Health Center EHR Data Messaging Platform Data
Effectiveness/patient (individual)	BMI Quality of Life (Sizing Them Up) ²⁶ Binge Eating ^{27,28} Parental Stress ²⁹ Acceptability ^a Feasibility ^a Satisfaction ^a	Health Center EHR Data Caregiver surveys Caregiver qualitative interviews
Adoption/health center (practice, staff)	Training components Package elements	Audit of training platform
Implementation/health center (practice)	Acceptability of PWMI Feasibility Fidelity Retention of patients/% patient completion of PWMI	<i>Healthy Weight Clinic</i> Staff interviews, observations Acceptability of Intervention Measure ³⁰ Feasibility of Intervention Measure ³⁰ Implementation Leadership Support, ³¹ short version ³² Implementation Climate ³³ Organizational Change Expectations, ³⁴ short version ³²
Maintenance/sustainability/health center (practice)	Cost and Budget Impact Sustainability of PWMI	Program Sustainability Assessment Tool ⁴⁴ Cost Collection Tool

^aMeasures to be determined if measured via survey or qualitative interviews.

EHR, electronic health record; PWMI, pediatric weight management intervention.

Implementation

We will measure acceptability, feasibility, and fidelity of the intervention at the provider level by using validated measures when available, such as the Weiner et al. surveys.³⁰ The fidelity measurement developed for the PWMI will be guided by the implementation plan and intervention protocol and has been previously used in our previous trial by observing delivery of care at the HWC. In addition, we will use validated surveys to assess implementation leadership support, implementation climate, and organizational change expectations.^{31–34} Staff who participate in training and implementation of the PWMI will be asked to complete these measures pre- and post-training and implementation. Leadership staff (*i.e.*, CEO, CFO, board members) at the pilot health centers may also complete these measures to gauge their perceptions of the intervention and its implementation. After implementing the program for 1 year, we will engage the providers and leadership staff in qualitative interviews to better refine the package. Cost will also be assessed as a primary measure of sustainability (see next section).

Maintenance/Sustainability

We will study the cost of the intervention and its implementation with a goal of informing clinicians, payers, and policymakers about what investment would be required to adopt and implement the intervention. To estimate costs of implementation, we will use time-driven activity-based costing approaches to estimate costs from the perspective of the community health center.³⁵ We

will follow guidelines from the U.S. Panel on Cost-Effectiveness in Health and Medicine for the assessment of costs from both a societal perspective and a third-party payer.^{36–38} All costs are reported in 2020 dollars with future costs discounted at 3% annually. Nonhealth care cost inputs are adjusted by using the Consumer Price Index. The costing protocol evaluates the incremental cost of implementation as compared with usual care and includes: (1) identification of the types of resources used; (2) measurement of the quantity of each resource used per person; and (3) valuation of resource utilization in monetary terms.

Discussion

Our use of implementation science frameworks in a systematic way is expected to aid in the successful adoption of the *Healthy Weight Clinic* PWMI to the pilot community health centers and will inform our final iteration of the PWMI for later large-scale dissemination.

Two other studies have used CFIR constructs to explore the preimplementation environment of community health centers planning to implement childhood obesity interventions.^{16,17} Of these, the original *Connect for Health* program identified key adaptations for implementation in additional community health centers nationally. These included changes to delivery of a best practice alert flagging elevated BMI in the EHR to noninterruptive, cultural adaptations to patient handouts and text messages, translation of patient handouts, and customized community resource

guides by site, among others.¹⁶ In a similar manner, by using CFIR constructs to inform our implementation strategies for *Healthy Weight Clinic* PWMI we expect to identify the adaptations that are needed. This strategy aligns with the previously recognized need to include implementation science frameworks early on to increase likelihood of the intervention's adoption and sustainability.²⁴

A recent literature search revealed the use of RE-AIM to evaluate the implementation of multiple PWMIs.^{39–41} These studies incorporated RE-AIM to determine barriers in their effort to implement a new intervention; however, they do not include the narrative of addressing the identified barriers post-pilot study. Further, evaluation using the RE-AIM framework also tends to be limited by the focus on a few rather than all of the constructs. Although reach and implementation gain much attention in the research world, in reality, all constructs are valued in achieving better implementation. Hennessy et al. conducted a systematic review of more than 39 interventions in early childhood by using the RE-AIM framework to assess their generalizability.⁴² The review demonstrated a greater need for in-depth reporting of external validity that could ultimately affect scale-up efforts. Similarly, another review conducted by McGoey et al. demonstrated that adoption, implementation, and maintenance were under-reported and that interventions should account for RE-AIM constructs for better generalizability.²¹ In our effort to prepare the PWMI for dissemination, we have incorporated all five constructs of RE-AIM into our Implementation Research Logic Model to facilitate a more integrated evaluation.

The use of CFIR and RE-AIM frameworks in other studies is largely limited to the use of each in a standalone manner, whereas our integrated use of both frameworks within a single logic model serves as a blueprint for comprehensively addressing implementation and evaluation. A potential limitation is that all the determinants delineated in our Implementation Research Logic Model may not act similarly as enablers or barriers to implementation in different CHCs, which could limit generalizability to future community health centers serving different patient populations with varying circumstances. However, the creation of the logic model itself should help identify many of these differences and delineate potential areas for adaptation needed for successful implementation in new community health centers.

Conclusion

Early incorporation of implementation science methods and frameworks is believed to enhance an intervention's likelihood of successful implementation and dissemination.⁴³ Our integrated use of CFIR constructs and the RE-AIM framework, conceptually linked to strategies using the Implementation Research Logic Model, represents a comprehensive strategy for evaluating and implementing *Healthy Weight Clinic* PWMI. Through this comprehensive approach, we anticipate wider spread and adoption of these evidence-based practices, which can mitigate disparities in access to treatment and thereby improve health and social outcomes for children.

Disclaimer

The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the US Government.

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